CENTER FOR DRUG REGULATION AND RESEARCH
EXTERNAL SERVICES

1.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER DRUGS (INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of cancer drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Cancer Drugs
Fees to be Paid	:	Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN CANCER DRUGS) ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information	

Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific) For imported products . License of pharmaceutical industries/importer/wholesaler (country specific) . Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format . Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality	Applicant Company/Manufacturer (For the whole Part I) FDA Website & Cashier

Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages	Applicant Company/Manufacturer (For the whole Part II): Quality Document

P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable) Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003 , Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving
	Queuing time of the application before decking to evaluators	None	21 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director
	Evaluates the application according to requirements and prescribed standards	None	130 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (for major deficiencies) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	78 working days	FDRO III
	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III or higher) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR. For Dangerous Drugs, prepares a letter/notification to PDEA to seek comments/ recommendations on the	None	1 working day	FDRO I/II

	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD Chief
	Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records *Personnel*

3. Receives the CPR/LOD/letter	Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 11215 Article VI, Section 23)			working days	

2.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS FOR HUMAN AND USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

This Certificate of Product Registration is granted to Marketing Authorization Holders of drug products upon compliance to the agency-prescribed Quality, Safety, Efficacy standards through the World Health Organization (WHO) **Collaborative Registration Procedure (CRP)** based on FDA-Circular-No.-2022-009. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of WHO Pre-qualified Pharmaceutical Products Monitored Release (MR) and Initial for WHO Pre-qualified drug products for human use including vaccines and biologicals
Fees to be Paid	:	A.O. No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA-Circular-No.2021-020 Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF

		The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF

ELIGIBILITY CRITERIA **(provided under Sec. V.B. of FDA-Circular-No.-2022-009)**
1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure. 2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT). 3. The eligible product shall be the same as the product prequalified by the WHO/PQT. a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission. b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT. 4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA-Circular-No.-2014-008 , its amendment FDA-Circular-No.-2014-008-A , supplement FDA-Circular-No.-2016-017 , and succeeding issuances for the same purposes.

5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.
GENERAL REQUIREMENTS
Accomplished application form as per FDA-Circular-No.-2014-003 , as prescribed in FDA-Advisory-No.2022-0001, or any future issuance providing for its amendment, repeal, or modification; Complete International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines (Refer to Annex 8.2 Checklist of Requirements for MR/Initial Applications of Vaccines and Biologicals). Appendix 3, Part A of WHO TRS 996 Annex 8, Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO) prequalified pharmaceutical product or vaccine) (Annex B). If the applicant company is not the original WHO PQ holder, the applicant company must submit an authorization letter that indicates agreement of the original WHO PQ holder, following the prescribed format in Appendix 3, Part A of WHO TRS 996; Country-specific requirements such as: Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers issued by Philippine FDA; Labeling materials consistent with country-specific requirements; Stability studies conducted under Climatic Zone IVb (hot and humid) for applicable products; Tabulated summary of WHO/PQT post-approval change/s prior to the registration application through CRP of WHO-prequalified pharmaceutical products and vaccines, obtained by the manufacturer/prequalification holder; Risk Management Plan (RMP) and RMP Philippine-specific Annex, with Periodic Safety Update Reports (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER), as applicable; Representative sample with corresponding Certificate of Analysis (upon request of the evaluator); and Additional requirements for vaccines and biological products: Identification of the medical director who will monitor event/s reactions, and prepare appropriate report to be submitted to FDA; Person/s responsible for production and control of the product (Name/s, Position, Department, and Sample of Signature); Information/procedure on the numbering system of the lots or batches; System for the reprocessing of the product in event of rejection of the lot or batch by the manufacturer’s Quality Assurance/Quality Control; Demonstration of lot-to-lot consistency from three (3) consecutive lots or batches; Description of the cold-chain procedures employed from the origin to the port of entry and storage in the Philippines (how and where);

Summary Lot Protocol (for vaccines, toxoids, and immunoglobulins only); List of countries where the product is already licensed and the date of approval (for vaccines only); and Head-to-head comparability studies (for biosimilars only).

CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION OF PHARMACEUTICAL PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant
Sec. A Introduction	Company/Manufacturer
Sec. B Overall ASEAN Common Technical Dossier	(For the whole Part I)
Table of Contents	
Sec. C Guidance on the Administrative Data and Product Information	
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	FDA Website & Cashier
Letter of Authorization (where applicable)	
Certifications	
For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	
Contract manufacturing agreement	
GMP certificate of contract manufacturer	
For manufacturing “under-license”	
License of pharmaceutical industries	
GMP certificate of the manufacturer	
Copy of “under-license” agreement	
For locally manufactured products:	
License of pharmaceutical industries	
GMP certificate (country specific)	
For imported products	

License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures	Applicant Company/Manufacturer (For the whole Part II: Quality)

S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable) Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1.General Aspect 2.Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1.Nonclinical Written Summaries 1.1.Introduction 1.2.General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1.Table of Contents 2.Pharmacology 2.1.Written Study Reports 2.1.1.Primary Pharmacodynamics 2.1.2.Secondary Pharmacodynamics 2.1.3.Safety Pharmacology 2.1.4.Pharmacodynamic Drug Interactions 3.Pharmacokinetics 3.1.Written Study Reports 3.1.1.Analytical Methods and Validation Reports 3.1.2.Absorption 3.1.3.Distribution 3.1.4.Metabolism 3.1.5.Excretion 3.1.6.Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7.Other Pharmacokinetic Studies 4.Toxicology 4.1Written Study Reports 4.1.1.Single-Dose Toxicity 4.1.2.Repeat-Dose Toxicity 4.1.3.Genotoxicity	

4.1.3.1.In vitro Reports	
4.1.3.2.In vivo Reports	
4.1.4.Carcinogenicity	
4.1.4.1.Long Term Studies	
4.1.4.2.Short- or Medium-Term Studies	
4.1.4.3.Other Studies	Applicant Company
4.1.5.Reproductive and Developmental Toxicity	/Manufacturer
4.1.5.1Fertility and Early Embryonic Development	
4.1.5.2.Embryo-Foetal Development	
4.1.5.3.Prenatal and Postnatal Development	Applicant Company
4.1.5.4.Studies in which the Offspring are Dosed and/or further Evaluated	/Manufacturer
4.1.6Local Tolerance	
4.1.7.Other Toxicity Studies (if available)	FDA (Applicant Company)
4.1.7.1.Antigenicity	
4.1.7.2.Immunotoxicity	
4.1.7.3.Dependence	
4.1.7.4.Metabolites	
4.1.7.5.Impurities	
4.1.7.6.Other	
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5.Overview of Safety	
6.Benefits and Risks Conclusions	
Sec. C Clinical Summary	
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1.1.Background and Overview	
1.2.Summary of Results of Individual Studies	

1.3.Comparison and Analyses of Results across Studies Appendix 1 2.Summary of Clinical Pharmacology Studies 2.Background and Overview 2.2.Summary of Results of Individual Studies 2.3.Comparison and Analyses of Results across Studies 2.4.Special Studies Appendix 2 3Summary of Clinical Efficacy 3.1Background and Overview of Clinical Efficacy 3.2.Summary of Results of Individual Studies 3.3Comparison and Analyses of Results across Studies 3.3.1.Study Populations 3.3.2.Comparison of Efficacy Results of all Studies 3.3.3.Comparison of Results in Sub-populations 3.4.Analysis of Clinical Information Relevant to Dosing Recommendations 3.5.Persistence of Efficacy and/or Tolerance Effects Appendix 3 4Summary of Clinical Safety 4.1.Exposure to the Drug 4.1.1.Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2.Overall extent of Exposure 4.1.3.Demographic and Other Characteristics of Study Population 4.2.Adverse Events 4.2.1.Analysis of Adverse Events 4.2.1.1.Common Adverse Events 4.2.1.2Deaths 4.2.1.3.Other Serious Adverse Events 4.2.1.4.Other Significant Adverse Events 4.2.1.5.Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3.Clinical Laboratory Evaluations 4.4.Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5.Safety in Special Groups and Situations 4.5.1.Patient Groups	

4.5.2.Drug Interactions 4.5.3.Use in Pregnancy and Lactation 4.5.4.Overdose 4.5.5Drug Abuse 4.5.6.Withdrawal and Rebound 4.5.7.Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5.Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1.Reports of Biopharmaceutic Studies 1.1.Bioavailability (BA) Study Reports 1.2.Comparative BA or Bioequivalence (BE) Study Reports 1.3.In vitro-In vivo Correlation Study Reports 1.4.Reports of Bioanalytical and Analytical Methods for Human Studies 2.Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1.Plasma Protein Binding Study Reports 2.2.Reports of Hepatic Metabolism and Drug Interaction Studies 2.3.Reports of Studies Using Other Human Biomaterials 3.Reports of Human Pharmacokinetic (PK) Studies 3.1.Healthy Subject PK and Initial Tolerability Study Reports 3.2.Patient PK and Initial Tolerability Study Reports 3.3Population PK Study Reports 4.Reports of Human Pharmacodynamic (PD) Studies 4.1Healthy Subject PD and PK/PD Study Reports 4.2.Patient PD and PK/PD Study Reports 5.Reports of Efficacy and Safety Studies 5.1.Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2.Study Reports of Uncontrolled Clinical Studies 5.3.Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4.Other Clinical Study Reports 6.Reports of Post-Marketing Experience 7.Case Report Forms and Individual Patient Listing	

Sec. F List of Key Literature References Additional Requirements: 1.Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2.Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020] Note: •ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2.Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement	Applicant Company/Manufacturer (For the whole Part I)

GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information	FDA Website & Cashier Applicant Company/Manufacturer (For the whole Part II): Quality Document

S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula	

P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: •ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable)	 Applicant Company/ Manufacturer Applicant Company/ Manufacturer

Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003, Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
A.O. No.47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	

. License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report . List of Countries where the product is already licensed and the date of approval (for vaccines) . Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) . Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients	

P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for Biosimilars	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology	

2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence	

4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies	

Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section*. *Decking to CRS is only applicable for Monitored release and Initial (Vaccines) applications	None	1 working day	CDRR Director

	Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	5 working days	FDRO I/II/III
	For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	31 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior Evaluator)
	2.5 Evaluates the application according to requirements and prescribed standards	None		FDRO I/II/III

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS)	None		FDRO I/II/III
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication **step 8a is only applicable for Monitored Release and Initial (Vaccines) applications.			
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	20 working days	FDRO III

	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for its recommendation on the application particularly on the formulation and labeling	None	2 working days	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None		FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None		FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/LOD/Letter	4.1 Releases the CPR/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
	4.2 Notifies the WHO/PQT of the regulatory decision (CPR/LOD/Letter)	None	Within 20 working days upon release of the regulatory decision (CPR/LOD/Letter)	FDRO I/II/III
(Service is covered under FDA-Circular-No.-2022-009).		TOTAL:	working days	

3.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PRESCRIPTION GENERIC DRUGS (INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of prescription generic drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS) ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	Applicant Company/Manufacturer

Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality	(For the whole Part I) FDA Website & Cashier

Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages	Applicant Company/Manufacturer (For the whole Part II): Quality Document

P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable) Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003 , Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	1 Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database	None	Day 1 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	Queuing time of the application before decking to evaluators	None	Day 2-21 20 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluator	None	Day 22 1 working day	LRD Chief
	Evaluates the application according to requirements and prescribed standards	None	Day 23-72 50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (for major deficiencies) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 working days	FDRO III

	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III or higher) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR. For Dangerous Drugs, prepares a letter/notification to PDEA to seek comments/ recommendations on the application.	None	Day 113 1 working day	FDRO I/II
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 114 1 working day	FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	Day 116 1 working day (per batch of applications)	LRD Chief
	Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	Day 119 1 working day (per batch of applications)	FDA Records *Personnel*
4. Receives the CPR/LOD/letter	Releases the CPR/LOD/letter to the client	None	Day 120 1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

4.ISSUANCE OF ACCREDITATION CERTIFICATE FOR LOCAL BIOEQUIVALENCE (BE) TESTING CENTERS (INITIAL and RENEWAL)

This Accreditation Certificate in granted to Bioequivalence (BE) Testing Centers conducting the clinical and bioanalytical phases of a BE Study upon site inspection to confirm compliance with principles of Good Clinical (GCP) and Laboratory Practices (GLP).

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	Bioequivalence (BE) Testing Centers (Clinical & Bioanalytical facilities)
Fees to be Paid	:	Based on Administrative-Order-No.-2012-0024 All fees with additional 1% Legal Research Fee (LRF) Accreditation of BE testing center (3-year validity): Php 20,000.00 (per year) Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) audit of BE testing centers Local Within Metro Manila: Php 15,000 + Transportation Cost Outside Metro Manila: Php 15,000 + Per Diem/Per inspector + Transportation Cost Overseas ASEAN Countries: US$3,500 + UNDP Per Diem Rate* + Transportation Cost Asia Pacific Countries (other than ASEAN): US$7,000 + UNDP Per Diem Rate + Transportation Cost All Countries Outside of Asia Pacific: US$10,500 + UNDP Per Diem Rate + Transportation Cost

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Documents to be submitted based on FDA Circular No.2021-006, Subject: Interim Guidelines on the Issuance of Accreditation and Inspection of Bioequivalence (BE) Testing Centers	
Letter of Request	Applicant
Proof of Payment, i.e. copy of Official Receipt (OR) or Oncoll payment slip	FDA Cashier
Organizational Chart	Applicant
Certificates of Accreditation and/or Licenses-to-Operate from relevant agencies	Relevant Agencies

Quality Manual	Applicant
Personnel Records including curricula vitae and training records demonstrating sufficient qualifications based on educational background, training and work experience	Applicant
Standard Operating Procedures (SOPs), Work Instructions, and forms of all the critical processes and activities	Applicant
Records/logbooks of instrument and equipment usage, maintenance, calibration and standardization	Applicant
Records of environmental monitoring and control (e.g. temperature, relative humidity, pests, microbes)	Applicant
Memoranda of Understanding/Contracts of Agreement between the Bioequivalence testing center and: Duly licensed/accredited 3rd party Screening Laboratory (for hematology, urinalysis, X-ray, ECG, drug testing, etc.) (where applicable) Duly licensed/accredited 3rd party Clinical or Bioanalytical Facility (where applicable) Other relevant parties involved in biological sample transport, waste disposal, instrument calibration, maintenance and standardization	Applicant
List of BE Studies Completed for the Past Accreditation Period and/or schedule of on-going and future studies	Applicant
Full Report of at least 2 Most-Recently Completed Bioequivalence Studies (for renewal applications)	Applicant
Other relevant documents in fulfillment of applicable principles of Good Clinical (GCP) and Good Laboratory Practices (GLP)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1.Manual Submission to FDAC Submit the letter of request and all other supporting documents (see table above) at the FDAC-PACD.	1.1.Issues acknowledgement receipt with a corresponding Document Tracking Number to the applicant.	See Table Above	1 working day	FDAC Personnel
2.Pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal				FDA Cashier/Landbank
	2.1.Endorses the received application to the Center	None	1 working day	FDAC Personnel

	2.2.Receives the application from FDAC and encodes /updates the database	None		Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit *Personnel*
	2.3 Decks/Assigns the application to the Bioequivalence (BE) Inspection Team Leader	None	1 working day	CDRR *Director*/Licensing and Registration Division (LRD) *Chief*
	2.4.Assigns co-inspectors and discusses the schedule of the desktop review	None	1 working day	BE Inspection *Team Leader* and *assigned members* of BE Inspection Team
	2.5.Conducts desktop review of the application based on the checklist of requirements	None	12 working days	BE Inspection Team
	2.6.Consolidates the evaluation findings of the Inspection Team	None	3 working days	BE Inspection Team
3.Submits any additional documents or clarifications requested by the BE Team	3.1..Sends the list of deficiencies to the applicant via email	None	20 working days	BE Inspection Team
	3.2.Evaluates the compliance documents submitted by the applicant	None	10 working days	BE Inspection Team
4.Confirms the schedule of virtual/remote inspection	4.Sends a proposed date of virtual/remote inspection to the applicant via email if necessary	None	1 working day	BE Inspection *Team Leader*
5.Participates in the opening and closing meetings at the BE Testing Center	5.1.Inspection Proper at the BE Testing Center, including conduct of opening and closing meetings, examination of	None	5 working days	BE Inspection Team

Provides overview of the BE Testing Center and conducts a brief tour at the site and its facilities Provides inspection-related documents and information as requested by the BE Inspection Team through observation and interview	documents with direct access, interviews, and observation of activities, equipment, and conditions in the inspected areas Provides the provisional list of inspection findings on the last day of inspection			
	5.2.Prepares the Official Inspection Report		Within 20 working days after the inspection	BE Inspection Team
	5.3.Reviews the Official Inspection Report, affixes initial on the draft document, and forwards it to the Section Supervisor		1 working day	BE Inspection Team
	5.4.Reviews and signs the Official Inspection Report, and forwards it to the Licensing and Registration (LRD) Chief			FDRO IV (Supervisor)
	5.5.Checks and endorses the recommendation of the inspectors and supervisor by affixing signature			LRD Chief
	5.6.Signs the Official Inspection Report		1 working day	CDRR Director
	5.7.Encodes/Updates the Database and Endorses the final output document to CDRR-Records	None	1 working day	CDRR-CRR Unit Personnel
	5.8.Scans and endorses the Inspection Report to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-Records *Personnel*

	5.9.Releases the Inspection Report to the client	None	1 working day	AFS Releasing Section *Personnel*
6.Submits the Corrective and Preventive Action (CAPA) Plan	6.1.Receives the Corrective and Preventive Action (CAPA) Plan and forwards it to the Center for Drug Regulation and Research (CDRR)	None	Client: Within 20 working days upon receipt of inspection report by the client. FDAC: 1 working day	FDAC Personnel
	6.2.Receives the Corrective and Preventive Action (CAPA) Plan from FDAC and encodes/updates the database and forwards it to the BE Inspection Team Leader	None	1 working day	CDRR-CRR Unit Personnel
	6.3.Evaluates the Corrective and Preventive Action (CAPA) Plan	None	Within 20 working days upon receipt of CAPA Plan	BE Inspection Team
7.Submits responses and documents requested by the BE Inspection Team, if applicable	7..1Prepares the Accreditation Certificate and Final Inspection Report if approval of the application is recommended Prepares and sends the Notice of Deficiencies (NOD) through email if information in the CAPA Plan or accompanying documents submitted are insufficient to make a final decision, then reviews the requested documents upon compliance by the BE Testing Center	None	Client: Within 20 working days upon receipt of NOD BE Inspection Team: 1 working day (for approval or disapproval); Within 20 working days upon receipt of	BE Inspection Team

	7.2.Prepares the Letter of Disapproval (LOD) and Final Inspection Report if approval of the application is not recommended		2nd compliance from the BE Testing Center, (for NOD)	
	7.3.Reviews the final output document (Accreditation Certificate or LOD), affixes initial on the draft document, and forwards it to the Section Supervisor	None		BE Inspection Team
	7.4.Reviews and signs the final output document, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	7.5.Checks and endorses the recommendation of the inspectors and supervisor by affixing signature	None		LRD Chief
	7.6.Signs and approves the final decision	None	1 working day	CDRR Director
	7.7.Encodes/Updates the Database and Endorses the final output document to the FDA Records Section (for Accreditation Certificate) or Releasing Section (for LOD)	None	1 working day	CDRR-CRR Unit Personnel
	7.8.Scans the Accreditation Certificate, updates the database, and endorses the Accreditation Certificate to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records *Personnel*
8.Receives the Accreditation Certificate or LOD	8.Releases the Accreditation Certificate or LOD to the client	None	1 working day	FDAC Releasing Section *Personnel*
TOTAL: Service is covered under the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products			112 working days	

5.ISSUANCE OF ACKNOWLEDGEMENT TO MINOR VARIATION-NOTIFICATION APPLICATIONS

This acknowledgment is issued to any minor changes to a registered pharmaceutical finished product classified as minor-variation notification.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf Refer to FDA-Circular-No.-2014-008 , Annex D Payment shall be on a per product, per change basis Regular PACs: Php500.00 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
FDA-Circular-No.-2014-008-A	
Hard copy:	
Two (2) copies of notarized Annex B (see attached sample Annex B);	Applicant company/ Manufacturer
Original copy of the Official Receipt.	FDA Cashier
Soft copy:	
Notarized latest Annex C;	
Portable document format (PDF) copy of signed integrated application form (IAF);	Applicant Company/ Manufacturer
IAF in Microsoft Excel format;	
Scanned copy of Certificate of Product Registration (CPR) and/or proof of renewal;	

For Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval (where applicable); Complete documentary requirements based on the ASEAN Variation Guidelines, FDA-Circular-No.-2014-008 , FDA-Circular-No.-2014-008-A , and FDA-Circular-No.-2016-017 and pertinent evidence supporting change/s	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph	1.1 Receives the application and forwards the application to CDRR pre-assessor	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN)	None	0	CDRR Personnel

2. Submits application with complete documents and requirements through fdac.letters.cdrr@fda.gov.ph	2.1.Accepts the application with complete and correct requirements. 2.2.Assigns Document Tracking Number (DTN) and issues pre-assessment slip to the applicant indicating to proceed to payment	None	1 working day	FDAC Personnel
3.Pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Upon payment, the applicant shall send the copy of the Official Receipt to the FDAC through email.		See Table Above	1 working day	FDA Cashier/ Landbank
	3.1 Endorses the received applications (soft/hard copies) to the Center, including the soft copy of transmittal for post-acknowledgement	None	1 working day	FDAC Personnel
	Evaluates the application according to requirements and prescribed standards	None	2 working days	CDRR Personnel

	Acknowledges the notification, encodes and updates the database and Document Tracking System status For approved applications, revises Annex C then emails to the applicant company For disapproved applications, emails the signed grounds for disapproval to the applicant company	None	2 working days	CDRR-CRR Personnel
Service covered under FDA-Circular-No.-2020-026.		TOTAL:	7 working days	

Note: Day 1 strictly refers to Tuesdays and Wednesdays which are the Notification days following FDA-Circular-No.-2014-008-A.

6.ISSUANCE OF BUREAU OF CUSTOMS (BOC) CLEARANCE [IMPORT PERMIT AND EXPORT PERMIT)

The BOC Clearance is granted to establishments with:

A. Valid LTO as drug Importer/Exporter to allow importation or exportation of drug products used as samples for registration, product development studies, and as test samples or reference products for Bioavailability/Bioequivalence studies, Comparative Dissolution Profile, Biowaiver, return of complaint samples.

B. Valid LTO as drug Sponsor/CRO for the return of unused Investigational Product/s and/or Ancillary supplies in an approved clinical trial conducted in the Philippines to the Sponsor or as specified by applicant, e.g. Global Depot.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Bureau of Customs Clearance [Import Permit and Export Permit]	
Letter of Application. It should include the following: Name of requesting party and position Purpose of application Itemized, detailed description of the drug product: Generic Name Brand Name (*if applicable*) Dosage Strength and Form Packaging/Availability Manufacturer Manufacturing Data *If the exact manufacturing data of the drug product is unavailable at the time of application, the applicant shall include in their letter a commitment on their part to submit the information once it became available. ·An estimated quantity/ volume needed ·Country of Origin (Indicate the country where the drug product will be shipped from) Receiving company and complete address (include name of representative if available) (*for export*)	Applicant Company/Manufacturer
·A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution.	Applicant
Proof of payment (Php 500 + LRF) per product	Company/Landbank/FDA Cashier
Certificate of Analysis (*for import*) / Actual photo of the drug product to be exported (*for export*)	
Proforma Invoice (includes batch number & expiry date)	Applicant Company/Manufacturer
Proof of Purchase (i.e. Official Receipt) from a reputable local source of the product (for export except for products which will be shipped by the MAH or for products intended for clinical trial use)	Applicant Company/Manufacturer
References: Republic Act No. 9711 – Food and Drug Administration Act of 2009 Customs Memorandum Circular No. 54-2014 – Matrix on Appropriate Requirements on the Release of Products under FDA Jurisdiction	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1.Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC Personnel
2.Pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then send the proof of payment to the FDAC.	2.1.Receives the payment from the applicant for posting Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	*Timeline starts after posting of payment	FDA Cashier/ Landbank FDAC Personnel
	2.2.Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff

	2.4.Evaluates the application for completeness according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the client through electronic communication (3 calendar days to respond to the queries)	None	3 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2.5.Reviews the evaluated application bearing the recommendation of the Evaluator	None	1 working day	Clinical Research Section *Supervisor*
	2.6.Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	2.7.Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief
	2.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	2.9.Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the permit or final response	3.Releases the permit or final response to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL:		PHP510.00 per product	7 Working Days	

7.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION FOR MAJOR VARIATION - STRAIN CLEARANCE (MAV-SC) AND MINOR VARIATION – STRAIN CLEARANCE (MIV-SC) OF HUMAN INFLUENZA VACCINES

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed change in the strains has been approved (MaV-SC)/to continue the manufacture, distribution and sale of Seasonal Influenza Vaccines based on compliance with quality, safety and efficacy standards (MiV-SC).

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Human Influenza Vaccines
Fees to be Paid	:	Major Variation – Strain Clearance (MaV-SC) Php 20,000 + LRF Minor Variation – Strain Clearance (MiV-SC) Php 500 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MAJOR VARIATION – STRAIN CLEARANCE (MaV-SC) OF HUMAN INFLUENZA VACCINES FDA Circular 2020-002: Guidelines on the Registration of Human Influenza Vaccines (Only relevant and adequate sections of the ACTD/CTD should be submitted. All sections not felt to be necessary should however be justified adequately in the Summary/Overview) Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Table of Contents Sec. C Guidance on the Administrative Data and Product Information	Applicant Company

For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	Applicant Company/Manufacturer
Contract manufacturing agreement	Applicant Company/Manufacturer
GMP certificate of contract manufacturer	Applicant Company/Manufacturer
For manufacturing “under-license”	
License of pharmaceutical industries	Applicant Company/Manufacturer
GMP certificate of the manufacturer	Applicant Company/Manufacturer
Copy of “under-license” agreement	Applicant Company/Manufacturer
For locally manufactured products:	
License of pharmaceutical industries	Applicant Company/Manufacturer
GMP certificate (country specific)	Applicant Company/Manufacturer
For imported products	
Foreign GMP Clearance	
License of pharmaceutical industries/importer/wholesaler (country specific)	Applicant Company/Manufacturer
Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin	Applicant Company/Manufacturer
according to the current WHO format	Applicant Company/Manufacturer
If the product is not marketed in the country of origin the following should be submitted:	
CPP indicating that the product is for export only or Certificate of Export; and	
Authenticated Certificate of Free Sale (CFS) or CPP where it is marketed;	Applicant Company/Manufacturer
If the country of origin does not issue a CPP the following should be submitted:	Applicant Company/Manufacturer
Justification that the country of origin does not issue a CPP; and	
Authenticated CFS or CPP where it is marketed	Applicant Company/Manufacturer
	Applicant Company/Manufacturer
Labeling (new strains)	

Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary (addendum to “previous” QOS) Sec. C Body of Data Drug Substance (S) S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials - seed lots: history: - passage level - characterization of Haemagglutinin and Neuraminidase - analytical protocols (including test results on seed lots)* S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation - monovalent bulks: - manufacturing process strain specific changes - validation of critical manufacturing steps (e.g. inactivation, splitting efficiency) (new strains) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures - validation study reports and summaries of test method [e.g. validation of Single Radial Diffusion (SRD) test for the new strain(s)] S 4.4. Batch Analyses - results of monovalent bulks: results (including test for neuraminidase): Each working seed lot from previously approved master seed lot where the procedure of working seed lot preparation is different from the approved procedure S 4.5. Justification of Specifications S 7 Stability (Stability tests on the active substances: results from monovalent bulks where they are used for more than	Applicant Company/Manufacturer (For the whole Part II: Quality Document)

Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients (new strains) P 3 Manufacture P 3.1. Batch Formula P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 8 Product Stability	
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable)	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document) Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: Representative Samples (w/COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System. Risk Management Plan Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) List of Countries where the product is already licensed and the date of approval Information on the number system of the lots or batches Summary Lot Protocol Lot to Lot Consistency from three (3) consecutive batches Copy of valid CPR	 Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company

Notarized Letter of Request for Major Variation – Strain Clearance (refer to Appendix 2) indicating the affected product, as well as declaration that there is/are no other change/s except from the update on the annual strain. This shall be signed by the Head of Regulatory Office. Adverse event following immunization report (summary of annual reports)	Applicant Company Applicant Company
CHECKLIST OF REQUIREMENTS FOR MINOR VARIATION – STRAIN CLEARANCE (MiV-SC) OF HUMAN INFLUENZA VACCINES	
Notarized Integrated Application Form (in excel and pdf format) (with proof of payment) Certifications	Applicant Company Applicant Company
For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	 Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	 Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
For locally manufactured products: a.License of pharmaceutical industries b.GMP certificate (country specific)	 Applicant Company/ Manufacturer Applicant Company/Manufacturer
For imported products a.Foreign GMP Clearance b. License of pharmaceutical industries/importer/wholesaler (country specific)	 Applicant Company/ Manufacturer

3.Labeling (new strains)	
4.Product Information	Applicant Company/Manufacturer
a. Package Insert	Applicant Company/Manufacturer
b. Summary of Product Characteristics (Product Data Sheet)	
4. Representative Samples (w/COA)	Applicant Company/Manufacturer
5. Risk Management Plan	Applicant Company/Manufacturer
6. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report **(PBRER)**	Applicant Company/Manufacturer
7. List of Countries where the product is already licensed and the date of approval	
8. Information on the number system of the lots or batches	Applicant Company/Manufacturer
10. Summary Lot Protocol	Applicant Company/Manufacturer
11. Copy of valid CPR	Applicant Company/Manufacturer
12. Notarized Letter of Request for Minor Variation – Strain Clearance (refer to Appendix	Applicant Company/Manufacturer
3) indicating the affected product, as well as declaration that there is/are no other change/s. This shall be signed by the Head of Regulatory Office.	Applicant Company/Manufacturer
13. Adverse event following immunization report (summary of annual reports)	Applicant Company/Manufacturer

*Where the seed virus is tested for extraneous agents using Polymerase Chain Reaction (PCR), these data should be included in this application

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.Secures a schedule of appointment / submission to FDAC E-mail submission:	1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

2.Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Personnel
3.For accepted applications, pays the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	3.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3.Queuing time of the application before decking to evaluators	None	5 working days	CDRR-CRR Unit Personnel
	3.4.Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD Chief

	3.5.Evaluates the application according to requirements and prescribed standards	None	23 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	3.6.Prepares a worksheet and drafts certification when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic	None	1 working day	FDRO I/II/III
	3.7.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	16 working days	FDRO III
	3.8.Prepares the final output document (Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	1 working day	FDRO I/II
	3.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III

	3.10.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	3 working days	FDRO IV (Supervisor)
	3.11.Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	3 working days (per batch of applications)	LRD Chief
	3.12.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.13.Encodes/Updates the Database and endorses the final output document (Certification/LOD/Letter) to the FDA-Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.14.Scans and emails the scanned copy of the final output document (Certification/LOD/ Letter) to the client; and endorses the final output document to the AFS- Releasing Section	None	2 working days (per batch of applications)	FDA-Records Personnel
4. Receives the Certification /LOD/letter	4.Releases the Certification /LOD to the client	None	1 working day	AFS-Releasing Section Personnel
TOTAL: Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31, wherein 60 working days was proposed instead of 180 working days.			60 working days^	

Additional processing time shall be applied if consequential changes that are related to the strain change are filed together with the MaV-SC.

8.ISSUANCE OF CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR AND MINOR VARIATION-PRIOR APPROVAL) VIA FACILITATED REGISTRATION PATHWAY (FRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA **(provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)**
The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA;

The applicant may avail of the following submission pathways under FRP, subject to certain conditions.
Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product application is within three (3) years from the date of approval of the RDRA/s.
The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

Applications for RDRA/s post-approval changes
A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s that approved the post approval changes.
Note: The date of RDRA approval to be reflected in Annex B shall be the date the post-approval change/s was/were approved by the RDRA.
Official approval letter or notification of the post-approval change/s from the identified RDRA/s.
For changes and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product (categorized as major variation [MaV]-1 based on the ASEAN Variation Guideline for Pharmaceutical Products and as adopted through FDA-Circular-No.-2014-008 or any amendment or latest issuance thereafter), Assessment Report from each of the identified RDRA/s shall be required.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating

the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular. The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched. See checklist of requirements below for additional requirements.

CHECKLIST OF REQUIREMENTS FOR POST-APPROVAL CHANGES FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) 3. Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	Pre-assesses the completeness of the application and verifies the application if indeed for the abridged/verification review pathway for post-approval changes. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1. Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	Decks/Assigns the application to the assigned evaluator of the Registration Section.	None	1 working day	CDRR Director
	Evaluates the application according to requirements and prescribed standards	None	16 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)

3. If an electronic notice of deficiencies0 (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) or Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication.	None		FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	5 working days	FDRO III
	Prepares the final output document (CPR/ Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	FDRO I/II/III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)

	Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	Signs and approves the final decision	None	1 working day	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/Certification/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	Scans, barcodes the final output document (CPR/Certification/ LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/Certification /LOD/Letter	4. Releases the CPR/ Certification /LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		TOTAL:	30 working days	

9.ISSUANCE OF CERTIFICATE OF PRODUCT REGUSTRATION FOR PHARMACEUTICAL PRODUCTS (VARIATION-TURNED-INITIAL APPLICATIONS)

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products
Fees to be Paid		Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Variation-turned-Initial: Branded: Php 15,000.00 + LRF Unbranded: Php 10,000.00 + LRF Monitored Release Status: New application: Php 33,333.33 + LRF (5-year validity); Pending application: Php 13,333.33 + LRF (paid for 3-years and will avail 5-year validity) (according to FDA Advisory No. 2021-2904) The Legal Research Fund (LRF) fee is the amount equivalent to one percent (1%) of the fee imposed

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LIST OF VARIATION-TURNED-INITIAL APPLICATIONS Mav-1: Change and/or additional indication/dosing regimen/patient population/inclusion of clinical indication extending the usage of the product MaV-4: Addition or replacement of the manufacturing site of the drugs product MaV-10: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf

For modified release oral dosage forms For other critical dosage forms such as sterile preparations MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of the capsule shell for modified release dosage form MaV-12: Change in the primary packaging material for sterile drug product Qualitative and quantitative composition and/or Type of container and/or nclusion of primary packaging material MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles) MiV-PA15: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline) For other non-critical dosage forms (e.g. oral liquid, external preparation) MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)] MiV-PA28: Change in primary packaging for non-sterile drug product Qualitative and quantitative composition and/or Type of container and/or Inclusion of the primary packaging material Additional route of administration Change of manufacturing site (same subsidiary) of the drug product	FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CHECKLIST OF REQUIREMENTS FOR VARIATION-TURNED INITIAL APPLICATIONS FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable) No.-2014-008 Annex D	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Personnel
3. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1.Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	3.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit

	3.3.Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit Personnel
	3.4.Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	CDRR Director
	3.5.Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) (from safety and efficacy evaluation, if applicable) when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			

	4.2 For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	4.3.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.4.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the Certificate	None	1 working day	FDRO I/II
	4.5.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.6.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	FDRO IV (Supervisor)

	4.7.Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD Chief
	4.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.9.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.10.Scans and barcodes the final output document (CPR/LOD/Letter); emails scanned copy of the final output document to the client; and endorses the final output document (hard copy) to the AFS Releasing Section.	None	1 working day (per batch of applications)	FDA Records *Personnel*
5. Receives the CPR/ LOD letter	5.Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

10.ISSUANCE OF CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR AND MINOR VARIATION-PRIOR APPROVAL) VIA FACILITATED REGISTRATION PATHWAY (FRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA
(provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)

The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA;
The applicant may avail of the following submission pathways under FRP, subject to certain conditions.
Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product

application is within three (3) years from the date of approval of the RDRA/s.
The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

Applications for RDRA/s post-approval changes
A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s that approved the post approval changes.
Note: The date of RDRA approval to be reflected in Annex B shall be the date the post-approval change/s was/were approved by the RDRA.
Official approval letter or notification of the post-approval change/s from the identified RDRA/s.
For changes and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product (categorized as major variation [MaV]-1 based on the ASEAN Variation Guideline for Pharmaceutical Products and as adopted through FDA-Circular-No.-2014-008 or any amendment or latest issuance thereafter), Assessment Report from each of the identified RDRA/s shall be required.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular.

The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched.

See checklist of requirements below for additional requirements.

CHECKLIST OF REQUIREMENTS FOR POST-APPROVAL CHANGES FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) roof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application and verifies the application if indeed for the abridged/verification review pathway for post-approval changes. If the application is acceptable,	None	0	CDRR Pre-assessor

	informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).			
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.2 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	2.3 Receives the application from FDAC and encodes/updates the database.	None	Day 1 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator of the Registration Section.	None	Day 2 1 working day	CDRR Director

	2.5 Evaluates the application according to requirements and prescribed standards	None	Day 3-18 16 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)
3. f an electronic notice of deficiencies0 (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) or Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 19-23 5 working days	FDRO III

	3.3 repares the final output document (CPR/ Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	Day 24 1 working day	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	3.5 eviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 25 1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 26 1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	Day 27 1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/Certification/LOD/Letter) to the FDA Records Section	None	Day 28 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/Certification/ LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 29 1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/Certification /LOD/Letter	4.Releases the CPR/ Certification /LOD/Letter to the client	None	Day 30 1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		**TOTAL:**	**30 working days**	

11.ISSUANCE OF CERTIFICATE FOR POST-APPROVAL CHANGES OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of WHO Pre-qualified Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA **(provided under Sec. V.B. of FDA-Circular-No.-2022-009)**
1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure. 2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT). 3. The eligible product shall be the same as the product prequalified by the WHO/PQT. a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission. b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT. 4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA-Circular-No.-2014-008, its amendment FDA-Circular-No.-2014-008-A, supplement FDA-Circular-No.-2016-017, and succeeding issuances for the same purposes. 5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.
GENERAL REQUIREMENTS
Documentary requirements: Accomplished application form as per FDA-Circular-No.-2014-003, as prescribed in FDA-Advisory-No.2022-0001, subject to any future issuance providing for its amendment, repeal, or modification; Letter of Request for Post-Approval Changes (Annex E); The official post-prequalification variation approval document issued by the WHO/PQT; and Documentary requirements following FDA-Circular-No.-2014-008 (Application Process and Requirements for Post-approval Changes of Pharmaceutical Products) and its amendment, FDA-Circular-No.-2014-008-A, or any future issuance providing for its repeal, further amendment, or modification.

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. 1.Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor
2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1.Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel

	2.2.Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR Director
	2.4.Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	5 working days	FDRO I/II/III
	2.5.Evaluates the application according to requirements and prescribed standards	None	8 working days	FDRO I/II/III

3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR)/Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	7 working days	FDRO III
	3.3.Prepares the final output document (CPR/Certificate LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR or Certificate	None	1 working day	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief

	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/Certificate/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/Certificate/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/Certificate/LOD/Letter	4.1 Releases the CPR/Certificate/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
	4.2 Notifies the WHO/PQT of the regulatory decision (CPR/Certificate/LOD/Letter)	None		FDRO I/II/III
(Service is covered under FDA-Circular-No.-2022-009).		TOTAL:	25 working days	

12.ISSUANCE OF CERTIFICATE OF PHARMACEUTICAL PRODUCTS (COPP), CERTIFICATE OF FREE SALE (CFS), EXPORT CERTIFICATE (EC), AND GENERIC LABELING EXEMPTION (GLE)

These certificates are issued to indicate that the product is registered and marketed in the country; or for export; or exempted from the generic labeling guidelines.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders
Fees to be Paid	:	COPP - Php 500.00 each/per product/per country + 1% LRF CFS - Php 500.00 each/per product/per country + 1% LRF EC - Php 500.00 each/per product/per country + 1% LRF GLE - Php 500.00 each/per product/per year for low volume of importation + 1% LRF Php 500.00/product for special handling + 1% LRF as per A.O. No. 50 s. 2001 (Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Certificate of Pharmaceutical Product	
Application Form	Applicant Company Applicant
Valid Certificate of Product Registration	Company Applicant Company
Valid License to Operate (LTO) of manufacturer/exporter	Applicant Company Applicant
Valid cGMP of manufacturer	Company Applicant Company
Immediate and secondary labeling materials	Applicant Company
Unit Dose Formulation	
Proof of Payment (per product/per country)	

Certificate of Free Sale	
Application Form	Applicant Company Applicant
Valid Certificate of Product Registration	Company Applicant Company
Valid License to Operate (LTO) of Manufacturer/exporter	Applicant Company
Proof of Payment (per product/per country)	
Export Certificate	Applicant Company Applicant
Application Form	Company Applicant Company
Valid Certificate of Product Registration	Applicant Company
Valid License to Operate (LTO)	Applicant Company
Quantity, batch number, manufacturing and expiry dates of the drug product/s to be exported	
Proof of Payment (per product/per country)	Applicant Company Applicant
Generic Labeling Exemption	Company Applicant Company
Completely filled and signed Integrated Application Form (in excel and pdf format)	Applicant Company Applicant
Signed Letter of Request (stating the basis of exemption)	Company Applicant Company
Copy of valid CPR with attachments, if applicable	
License to Operate as Drug Importer (for low volume of importation)	
Facsimile of the labeling materials (primary and secondary packaging materials)	Applicant Company
Copy of previously approved certificate of generic labeling exemption (for renewal applications)	
Market forecast for the period applying for, in case of low volume of importation	Applicant Company
(must be specified monthly and separated with the letter of request)	
Proof of Payment	
References:	
A.O. No. 2016-0008 - Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use	
DOH Administrative Order (AO) No. 105, s. 1991 - Requirement for Labelling Materials of Veterinary Drugs and Products	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment.	None		CDRR *Personnel*
	If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre- assessment and new Document Tracking Number (DTN).			
For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR)
				– Central Receiving and Releasing (CRR) Unit

	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD Chief/ CRR Unit *Personnel*
	3.4 Evaluates the application according to requirements and prescribed standards	None	11 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior)*
If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certification issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	3 working days	*FDRO I/II*
	4.2 Prepares the final output document (Certification /LOD), affixes initial, and forwards it to the Section Supervisor	None	1 working day	*FDRO I/II*
	4.3 Reviews the final output document, signs and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	4.4 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*

	4.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.6 Encodes/Updates the Database and endorses the final output document to the AFS Releasing Section	None	2 working days (per batch of applications)	*CDRR-CRR Unit Personnel*
5. Receives the Certification /LOD	5.1 Releases the Certification /LOD to the client	None	1 working day	*AFS Releasing Section Personnel*
TOTAL:			**20 working days**	

13.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR BIOLOGICALS AND VACCINES (NEW CHEMICAL ENTITIES/MONITORED RELEASE AND INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Biologics and Vaccines which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Vaccines, Biologicals, stem cell, and blood and blood products
Fees to be Paid	:	New Chemical Entities/Monitored Release Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Variation-turned-Initial:

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS	
A.O. No. 47-a s.2011 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
. License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report . List of Countries where the product is already licensed and the date of approval (for vaccines) . Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA . Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) . Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	Applicant Company/ Manufacturer (For whole Part II: Quality)
Drug Product (P) P 1 Description and Composition	

P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses	

Summary Lot Protocol (for vaccines, toxoids and immunoglobulins based on FDA Advisory 2021-2037) Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for biosmilars	
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2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution	

3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References	Applicant Company/Manufacturer

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4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies	
4.1.2. Overall extent of Exposure	
4.1.3. Demographic and Other Characteristics of Study Population	
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4.2.1. Analysis of Adverse Events	
4.2.1.1. Common Adverse Events	
4.2.1.2. Deaths	
4.2.1.3. Other Serious Adverse Events	
4.2.1.4. Other Significant Adverse Events	
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4.5.1. Patient Groups	
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4.5.4. Overdose	
4.5.5. Drug Abuse	
4.5.6. Withdrawal and Rebound	
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5. Synopses of Individual Studies	
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Sec. E Clinical Study Reports (if applicable)	
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2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP. 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacture Applicant Company/Manufacturer
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Sec. B Overall ASEAN Common Technical Dossier	Applicant
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1. Integrated Application Form (with proof of payment)	
2. Letter of Authorization (where applicable)	Applicant
3. Certifications	Company/Manufacturer
For contract manufacturing:	(For the whole Section C)
a. License of pharmaceutical industries and contract manufacturer	FDA Website & Cashier
b. Contract manufacturing agreement	
c. GMP certificate of contract manufacturer	
For manufacturing “under-license”	
a. License of pharmaceutical industries	
b. GMP certificate of the manufacturer	
c. Copy of “under-license” agreement	
For locally manufactured products:	
a. License of pharmaceutical industries	
b. GMP certificate (country specific)	
For imported products	
License of pharmaceutical industries/importer/wholesaler (country specific)	
Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format	
Foreign GMP Clearance	
4. Site Master File	
5. Labeling	
6. Representative Sample with corresponding Certificate of Analysis	
7. Product Information	
Package Insert	
Summary of Product Characteristics (Product Data Sheet)	
8. Risk Management Plan (RMP)	
9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report	

10. List of Countries where the product is already licensed and the date of approval 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
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S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
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P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Quality Comparability P 9.1. Reference Biotherapeutic Product P 9.2. Manufacturing Process P 9.3. Characterization P 9.3.1. Physicochemical Properties P 9.3.2. Biological Activity P 9.3.3. Immunochemical Properties P 9.3.4. Impurities P 9.4. Specifications P 9.5. Analytical Techniques P 9.6. Stability	
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2.1. In Vitro Studies 2.2. In Vivo Studies	
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/ Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements: 1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer (For Whole Part IV: Clinical Document) Applicant Company Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*
	1.1.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR *Personnel*

2.For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	2.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/Landbank FDAC *Personnel*
	2.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR)
	2.3.Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	20 working days	CDRR-CRR Unit *Personnel*
	2.4.Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR *Director*

	2.5.Evaluates the application according to requirements and prescribed standards The registration evaluator determines if the application should be reviewed as a standalone biotherapeutic product or biosimilar then refers the RMP and PMS Protocol (for MR only), safety and efficacy to CRS for evaluation. If the product is classified as a vaccine, toxoid, or immunoglobulin, review of the Summary Lot Protocol is referred to the Common Services Laboratory- Vaccines and Biologics Unit (CSL-VBU).	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

	a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS).	None		*FDRO I/II/III/ Medical Specialist II*

	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.6.Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	40 working days	*FDRO III*
	2.7.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	*FDRO II*

	2.8.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None	1 working day	*FDRO III*
	2.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	2.10.Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	2.11.Signs and approves the final decision	None	1 working day	*CDRR Director*
	2.12.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA-Records Section	None	1 working day	*CDRR-CRR Unit Personnel*
	2.13.Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	1 working day (per batch of applications)	*FDA-Records Personnel*
3.Receives the CPR/LOD/letter	3.Releases the CPR/LOD/letter to the client.	None	1 working day	*AFS - Releasing Section Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, Republic Act No. 7394 Article 31, and Republic Act No. 11215 Article VI Section 23).			120 working days	

14.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER DRUGS (NEW CHEMICAL ENTITIES/MONITORED-RELEASE)

This Certificate of Product Registration is granted to Marketing Authorization Holders of cancer drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Cancer Drugs
Fees to be Paid	:	FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION	

ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information	Applicant Company/Manufacturer (For the whole Part I)
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications	FDA Website & Cashier
For contract manufacturing: . License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	
For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	
For imported products . License of pharmaceutical industries/importer/wholesaler (country specific) . Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format . Foreign GMP Clearance	
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information	

Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition	Applicant Company/Manufacturer (For the whole Part II: Quality)

P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable)	

Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2. Content of Nonclinical Written and Tabulated Summaries 2.1. Pharmacology 2.1.1. Written Summary 2.1.1.1. Primary Pharmacodynamics 2.1.1.2. Secondary Pharmacodynamics 2.1.1.3. Safety Pharmacology 2.1.1.4. Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2. Pharmacokinetics 2.2.1. Written Summary 2.2.1.1. Absorption 2.2.1.2. Distribution 2.2.1.3. Metabolism 2.2.1.4. Excretion 2.2.1.5. Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3. Toxicology 2.3.1. Written Summary 2.3.1.1. Single-Dose Toxicity 2.3.1.2. Repeat-Dose Toxicity 2.3.1.3. Genotoxicity 2.3.1.4. Carcinogenicity 2.3.1.5. Reproductive and Developmental Toxicity 2.3.1.5.1. Fertility and Early Embryonic Development 2.3.1.5.2. Embryo-Foetal Development 2.3.1.5.3. Prenatal and Postnatal Development	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

2.3.1.6. Local Tolerance 2.3.1.7. Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3. Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

4.1.5.2. Embryo-Fetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2	

3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data	

Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports 1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable)	

RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1.Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	2.2.Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	21 working days	CDRR-CRR Unit *Personnel*
	2.4.Decks/Assigns the application to the assigned evaluators of Registration Section and Clinical Research Section.	None	1 working day	CDRR *Director*
	2.5.Evaluates the application according to requirements and prescribed standards	None	130 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)/ Medical Specialist II*
If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	.a. Clinical Research Section (Safety and Efficacy evaluator) 2.6. Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP,	None		*FDRO I/II/III/ Medical Specialist II/III*

	and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.7.Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	78 working days	FDRO III
	2.8.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for the approval of the application	None	1 working day	FDRO I/II
	2.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III

	2.10.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	2.11.Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day (per batch of applications)	LRD Chief
	2.12.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	2.13.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	2.14.Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
3. Receives the CPR/LOD/letter	3.Releases the CPR/LOD/letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under Republic Act No. 11215 Article VI, Section 23)		TOTAL:	240 working days	

15.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER VACCINES AND BIOLOGICALS (NEW CHEMICAL ENTITIES/MONITORED-RELEASE AND INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Biologics and Vaccines which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Anti-Cancer Vaccines, Biologicals, stem cell, and blood and blood products
Fees to be Paid	:	**New Chemical Entities/Monitored Release** Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF **Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS	
A.O. No. 47-a s.2011 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier able of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
1. Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
3. Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval (for vaccines) 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Departmen t, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture	

P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control • Information on the number system of the lots or batches • System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses • Summary Lot Protocol (for vaccines, toxoids and immunoglobulins based on FDA Advisory 2021-2037) • Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for biosmilars	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary	

3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies	

4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
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Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information 1. Integrated Application Form (with proof of payment) 2. Letter of Authorization (where applicable) 3. Certifications For contract manufacturing: a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer For manufacturing “under-license” a. License of pharmaceutical industries	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer (For the whole Section C) FDA Website & Cashier

b. GMP certificate of the manufacturer c. Copy of “under-license” agreement For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance 4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis 7. Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
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P 8 Product Stability P 9 Quality Comparability P 9.1. Reference Biotherapeutic Product P 9.2. Manufacturing Process P 9.3. Characterization P 9.3.1. Physicochemical Properties P 9.3.2. Biological Activity P 9.3.3. Immunochemical Properties P 9.3.4. Impurities P 9.4. Specifications P 9.5. Analytical Techniques P 9.6. Stability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Consideration 2. Special Consideration 2.1. In Vitro Studies 2.2. In Vivo Studies	Applicant Company/Manufacturer (For Whole Part III: Nonclinical Document)
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/ Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements:	Applicant Company/Manufacturer (For Whole Part IV: Clinical Document) Applicant Company Applicant Company

1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC :-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: • BANCNET	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*

• Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	21 working days	CDRR-CRR Unit *Personnel*
	2.4 Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR *Director*
	2.5 Evaluates the application according to requirements and prescribed standards The registration evaluator determines if the application should be reviewed as a standalone biotherapeutic product or biosimilar then refers the RMP and PMS Protocol (for MR only), safety and efficacy to CRS for evaluation. If the product is classified as a vaccine, toxoid, or immunoglobulin, review of the Summary Lot Protocol is referred to the Common Services Laboratory- Vaccines and Biologics Unit (CSL-VBU).	None	130 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

	Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS).	None		*FDRO I/II/III/ Medical Specialist II*

	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	78 working days	*FDRO III*
	2.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	*FDRO II*
	2.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None	1 working day	*FDRO III*
	2.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	2.10 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	2.11 Signs and approves the final decision	None	1 working day	*CDRR Director*

	2.12 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA-Records Section	None	1 working day	*CDRR-CRR Unit Personnel*
	2.13 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	1 working day (per batch of applications)	*FDA-Records Personnel*
3. Receives the CPR/LOD/letter	3. Releases the CPR/LOD/letter to the client.	None	1 working day	*AFS - Releasing Section Personnel*
(Service is covered under Republic Act No. 11215 Article VI, Section 23)	**TOTAL:**		**240 working days**	

16.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR HERBAL MEDICINE/TRADITIONALLY-USED HERBAL PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Herbal Medicines and Traditionally Used Herbal Product which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products (Herbal and Traditionally-Used Herbal Medicines)
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF HERBAL MEDICINES Administrative-Order-No.-172-s.-2004 Guidelines on the Registration of Herbal Medicines	
Notarized Integrated Application Form (in excel and in pdf format)	
Proof of Payment	Applicant Company
Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company
Unit Dose and Batch Formulation	Applicant Company/Manufacturer
Technical Specifications of all Raw Materials	
Certificate of Analysis of active Raw Material(s)	Applicant Company/Manufacturer
From supplier of Active Raw Material	Applicant Company/Manufacturer
From manufacturer of finished product	Applicant Company (API Supplier & Manufacturer)
Certification of Authenticity of Plant Specimen from the National Museum or any FDA-recognized Taxonomist	
Technical Specifications of Finished Product	National Museum or any FDA-recognized Taxonomist
Certificate of Analysis (CA) of Finished Product from the same batch of representative sample)	
Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Applicant Company/Manufacturer
Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/Manufacturer
Stability Studies	Applicant Company/Manufacturer
Labeling Materials (facsimile)	
Evidence of Safety and Efficacy	
Representative Sample (upon request of the evaluator	NIRPROMP & Applicant Company
Additional Requirements: For herbal medicines validated by the National Integrated Research Program on Medicinal Plants (NIRPROMP), Copy of the Memorandum of Agreement between NIRPROMP and the applicant; otherwise, a copy of approval of FDA Committee on the registration of the said herbal medicine.	

For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	Applicant Company/ Manufacturer
For imported products:	
Certificate of Pharmaceutical Product (CPP)	Applicant Company/ Manufacturer
Foreign GMP Clearance	
Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF TRADITIONALLY-USED HERBAL PRODUCTS	
Administrative-Order-No.-184-s.-2004	
Guidelines on the Registration of Traditionally-Used Herbal Products	
	Applicant Company
Notarized Integrated Application Form (in excel and in pdf format)	Applicant Company
Proof of Payment	Applicant Company/Manufacturer
Valid agreements between the manufacturer, trader, importer, distributor, where applicable	
Unit Dose and Batch Formulation	Applicant Company/Manufacturer
Technical Specifications of all Raw Materials	Applicant Company/Manufacturer
Certificate of Analysis of active Raw Material(s)	Applicant Company (API Supplier &
From supplier of Active Raw Material	Finished Product Manufacturer)
From manufacturer of finished product	
Certification of Authenticity of Plant Specimen from the National Museum or any FDA -recognized Taxonomist	National Museum or any FDA-recognized Taxonomist
Technical Specifications of Finished Product	
Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/ Manufacturer
Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging	
Procedure (including specification for container closure system)	Applicant Company/ Manufacturer
Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
Stability Studies	Applicant Company/ Manufacturer

Labeling Materials (facsimile labels)	Applicant Company/ Manufacturer
Evidence of Safety	Applicant Company/ Manufacturer
Evidence of Claimed Application	Applicant Company/ Manufacturer
Representative Sample	Applicant Company/ Manufacturer
Additional Requirements:	
For products in plastic container:	Applicant Company/ Manufacturer
Certificate of Analysis for Test of Migratable Substances/ Leachability	Applicant Company/ Manufacturer
For imported products:	Applicant Company/ Manufacturer
Certificate of Traditionally –Used Herbal Product	
Foreign GMP Clearance	Applicant Company/ Manufacturer
Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment /submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3.For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section	None	1 working day	*CDRR Director*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	**a. Clinical Research Section (Evidence of Safety and Efficacy evaluator)** Prepares a worksheet with Recommendations on the evaluated evidence of safety and efficacy, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. **b. Registration Section (Quality evaluator)** Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Evidence of Safety & Efficacy received from the CRS).	None	1 working day	*FDRO I/II/III/ Medical Specialist II*
	3.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	3.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO II*
	3.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	3.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	3.10 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD *Chief*
	3.11 Signs and approves the final decision	None	1 working day	CDRR Director
	3.12 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.13 Scans, barcodes, and emails the scanned copy of the document to the client; and endorses the final output document to the AFS - Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31.			**120 working days**	

17.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR MEDICAL GRADE OXYGEN (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Medical Gases which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Medical Grade Oxygen
Fees to be Paid	:	**nitial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF MEDICAL GRADE OXYGEN	
1. Notarized Integrated Application Form (in excel and in pdf format)	FDA Website
2. Proof of payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/ Manufacturer
4. Technical Specifications of Finished Product	Applicant Company/ Manufacturer
5. Certificate of Analysis (CA) of Finished Product	Applicant Company/ Manufacturer
6. Certificate of Analysis issued by CIGI for the product	CIGI
7. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls	Applicant Company/ Manufacturer

8. Complete quality control procedures for the finished product.	Applicant Company/ Manufacturer
9. Philippine Standard Quality Certification Mark issued by the Bureau of Product Standards, Department of Trade and Industry	Bureau of Product Standards, Department of Trade and Industry
10. Labeling Materials (facsimile)	Applicant Company/Manufacturer
11. For imported products: Foreign GMP Clearance	FDA CDRR
12. Copy of valid License to Operate	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secures a schedule of appointment / submission to FDAC.	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre- assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	L Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators	None	9 working days	
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	23 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended	None	1 working day	*FDRO I/II/III*
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E- NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	12 working days	*FDRO III*

	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*FDRO III*
	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	3 working days (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	3 working days (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*

	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	2 working days (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 60 working days was proposed instead of 180 working days).		**TOTAL:**	60. **working days**	

18.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDY DRUG PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Over -the-Counter Drugs and Household Remedy preparations which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity (Based on Bureau Circular No. 5 s.1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDIES	
1. Notarized Integrated Application Form (in excel and in pdf format)	
2. Proof of payment	FDA Website
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	FDA Cashier

4. Unit Dose and Batch Formulation	Applicant Company /Manufacturer
5. Technical Specifications of all Raw Materials	
6. Certificate of Analysis of Active Raw Material(s)	Applicant Company /Manufacturer
a. From supplier of API	Applicant Company/ Manufacturer
b. From manufacturer of finished product	Applicant Company /Manufacturer
7. Technical Specifications of Finished Product	(Supplier of API & Manufacturer)
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging	Applicant Company/ Manufacturer
Procedure (including specification for container closure system)	Applicant Company /Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
11. Stability Studies	Applicant Company /Manufacturer
12. Labeling Materials (facsimile labels)	FDA CDRR (Applicant Company)
13. Representative Samples (w/ COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System (upon request of the evaluator).	
Additional Requirements:	
14. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	
15. For imported products:	
a. Certificate of Pharmaceutical Product (CPP) or Certificate of Free Sale	
b. Foreign GMP Clearance	
16. Valid LTO (Importer/Manufacturer/Distributor/Trader)	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	L Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	L Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD)when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	*FDRO I/II/III*
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Serviced is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 120 working days was proposed instead of 180 working days).		**TOTAL:**	**120 working days**	

19.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF NEW DRUG PRODUCTS FOR HUMAN AND VETERINARY USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE VERIFICATION REVIEW PATHWAY

This Certificate of Product Registration or Certification is granted to Marketing Authorization Holders of drug products classified under Monitored Release either as a New Drug/New Chemical Entity or a pharmaceutical/therapeutic innovation of a Tried and Tested/Established Drug (i.e., involving use for a new indication, a new mode of administration, a new dosage form, a new dosage strength, and/or a new fixed-dose combination of two or more active ingredients) upon compliance to the agency-prescribed Quality, Safety, Efficacy standards through the **Verification Review Pathway** based on F FDA-Circular-No.2022-004.
It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products • Monitored Release (MR) for human and veterinary drug products • MR for human and animal vaccines and biologicals
Fees to be Paid	:	Administrative-Order-No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

ELIGIBILITY CRITERIA **(Provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)**
1. The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA; 2. The applicant may avail of the following submission pathways, subject to certain conditions.

a. Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
b. Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product application is within three (3) years from the date of approval of the RDRA/s.
c. The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
3. The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
4. The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
5. The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
6. All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

1. Applications for new drugs, vaccines, and biologicals
a. A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s.
b. Assessment Report from each of the identified RDRA/s.
c. A valid Certificate of Pharmaceutical Product (CPP) following the WHO Certification Scheme or its equivalent from the identified RDRA/s. If the product is not marketed in the jurisdiction of the identified RDRA/s, then a valid CPP or its equivalent from any of the RDRA/s as listed in Annex A may be provided.
d. Complete International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines. (See detailed checklist of requirements below).
e. Complete documentary requirements submitted to the RDRA's following the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).
f. A report of stability studies conducted under climatic Zone IVB (hot and very humid), with the required minimum time period covered by data at submission, the minimum number of batches, and storage conditions for accelerated and long-term conditions shall be provided unless otherwise justified.

g. Proposed Package Insert/Patient Information Leaflet identical to that approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular.

The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched.

CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION OF PHARMACEUTICAL PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant
Sec. A Introduction	Company/Manufacturer
Sec. B Overall ASEAN Common Technical Dossier	(For the whole Part I)
Table of Contents	
Sec. C Guidance on the Administrative Data and Product Information	
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	FDA Website & Cashier
Letter of Authorization (where applicable)	
Certifications	
For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	
Contract manufacturing agreement	
GMP certificate of contract manufacturer	
For manufacturing “under-license”	
License of pharmaceutical industries	
GMP certificate of the manufacturer	
Copy of “under-license” agreement	

For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures	Applicant Company/Manufacturer (For the whole Part II: Quality)

S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities	

P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable) Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2. Content of Nonclinical Written and Tabulated Summaries 2.1. Pharmacology 2.1.1. Written Summary 2.1.1.1. Primary Pharmacodynamics 2.1.1.2. Secondary Pharmacodynamics 2.1.1.3. Safety Pharmacology 2.1.1.4. Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2. Pharmacokinetics 2.2.1. Written Summary 2.2.1.1. Absorption 2.2.1.2. Distribution 2.2.1.3. Metabolism 2.2.1.4. Excretion 2.2.1.5. Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3. Toxicology 2.3.1. Written Summary 2.3.1.1. Single-Dose Toxicity 2.3.1.2. Repeat-Dose Toxicity 2.3.1.3. Genotoxicity 2.3.1.4. Carcinogenicity 2.3.1.5. Reproductive and Developmental Toxicity 2.3.1.5.1. Fertility and Early Embryonic Development	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

2.3.1.5.2. Embryo-Foetal Development	
2.3.1.5.3. Prenatal and Postnatal Development	
2.3.1.6. Local Tolerance	
2.3.1.7. Other Toxicity Studies (if available)	
2.3.2. Tabulated Summary	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)
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Sec. D Nonclinical Study Reports	
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2.1.3. Safety Pharmacology	
2.1.4. Pharmacodynamic Drug Interactions	
3. Pharmacokinetics	
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3.1.2. Absorption	
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3.1.4. Metabolism	
3.1.5. Excretion	
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4.1.2. Repeat-Dose Toxicity	
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4.1.3.2. In vivo Reports	
4.1.4. Carcinogenicity	
4.1.4.1. Long Term Studies	Applicant Company /Manufacturer
4.1.4.2. Short- or Medium-Term Studies	Applicant Company /Manufacturer
4.1.4.3. Other Studies	FDA (Applicant Company)
4.1.5. Reproductive and Developmental Toxicity	
4.1.5.1. Fertility and Early Embryonic Development	
4.1.5.2. Embryo-Foetal Development	
4.1.5.3. Prenatal and Postnatal Development	

4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations	

3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports 1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	

2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
A.O. No. 47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format	Applicant Company/ Manufacturer Applicant Company/ Manufacturer

Foreign GMP Clearance	Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report List of Countries where the product is already licensed and the date of approval (for vaccines) Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
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S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
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2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies	

4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	

2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products A.O. No.-2014-0016 Adoption of the World Health Organization “Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)” for the Registration of Biosimilar Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company

Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information	Applicant Company /Manufacturer Applicant Company/ Manufacturer

Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures	

P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Consideration 2. Special Consideration	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements: 1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP. 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF VETERINARY DRUGS, VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website
2. Proof of Payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company/Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/Manufacturer
6. Certificate of Analysis of active Raw Material(s)	Applicant Company/
a. From supplier of API	Manufacturer
b. From manufacturer of finished product	(Supplier of API & Manufacturer)
7. Technical Specifications of Finished Product	Applicant Company/ Manufacturer
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/ Manufacturer
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Applicant Company/ Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/
11. Stability Studies	Manufacturer
12. Labeling Materials (facsimile labels)	Applicant Company/
13. Representative Sample (upon request of the evaluator)	Manufacturer
	Applicant Company/
Additional Requirements:	Manufacturer
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	
2. For imported products:	Applicant Company/
a. Certificate of Pharmaceutical Product (CPP)	Manufacturer
b. Foreign GMP Clearance	Applicant Company/
3. For new veterinary drugs:	Manufacturer
a. Pre-clinical studies	
b. Protocol for monitored release	

4. For fixed-dose combination: Rationale of the Combination	Applicant Company/ Manufacturer
5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Applicant Company/ Manufacturer FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Secure a schedule of appointment / submission to FDAC -mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2 Pre-assesses the completeness of the application and verifies the registration pathway of the application if indeed for verification review. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator of the Registration Section. For human vaccines and biologicals, determines if the application is MR and refers the RMP and PMS Protocol (if any) to the Clinical Research Section (CRS) for evaluation. For human drug products, simultaneously decks the RMP and PMS Protocol (if any) to CRS for evaluation.	None	1 working day	CDRR *Director* CDRR-CRR
	2.4 Evaluates the application according to requirements and prescribed standards For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	16 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)*

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		*FDRO I/II/III*
	2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	5 working days	FDRO III
	3 Prepares the final output document (CPR /LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for its recommendation on the application particularly on the formulation and labeling	None	1 working day	FDRO I/II/III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)

	Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/LOD/Letter	4. Releases the CPR/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		**TOTAL:**	**30 working days**	

20.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDY DRUG PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Over -the-Counter Drugs and Household Remedy preparations which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity (Based on Bureau Circular No. 5 s.1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDIES	
1. Notarized Integrated Application Form (in excel and in pdf format)	FDA Website
2. Proof of payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company /Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company /Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/ Manufacturer

6. Certificate of Analysis of Active Raw Material(s)	Applicant Company /Manufacturer
a. From supplier of API	(Supplier of API & Manufacturer)
b. From manufacturer of finished product	Applicant Company/ Manufacturer
7. Technical Specifications of Finished Product	Applicant Company /Manufacturer
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company /Manufacturer
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
11. Stability Studies	
12. Labeling Materials (facsimile labels)	
13. Representative Samples (w/ COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System (upon request of the evaluator).	
Additional Requirements:	
14. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	
15. For imported products:	
a. Certificate of Pharmaceutical Product (CPP) or Certificate of Free Sale	
b. Foreign GMP Clearance	
16. Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR (Applicant Company)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior*

				Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD)when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	*FDRO I/II/III*
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Serviced is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 120 working days was proposed instead of 180 working days).		**TOTAL:**	**120 working days**	

21.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PHARMACEUTICAL PRODUCTS (ELECTRONIC AUTOMATIC RENEWAL) [e-AR]

This Certificate of Product Registration is granted by the FDA to the Marketing Authorization Holder in order to continue marketing a specific product in the country provided that the conditions for Automatic Renewal stipulated in Book II Article 1 Section 3.B (2) of the IRR of RA 9711 have been fulfilled.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products for Human and Veterinary Use
Fees to be Paid	:	Administrative-Order-No.-50-2001 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Eligibility to Automatic Renewal Registration Implementing Rules and Regulations (IRR) of Republic Act No. 9711 There shall be automatic renewal of the Certificate of Product Registration (CPR) when the following conditions are satisfied: The application is filed before the expiration date of the registration; The prescribed renewal fee is paid upon filing of the application; and A sworn statement indicating no change or variation whatsoever in the product is attached to the application.	Applicant Company

References: Republic Act 9711 – Food and Drug Administration Act of 2009 The Rules and Regulations Implementing Republic Act No. 9711 – The Food and Drug Administration Act of 2009 FDA-Advisory-No.2021-0999 - Implementation of The Food and Drug Administration (FDA) eServices Portal System for Automatic Renewal (AR) Applications for Drug Products.	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1.Access the online application portal through (http://eservices.fda.gov.ph) “Applications“		None	0	Applicant
1.2.Select “Certificate of Product Registration” and select “Drug”. Select the classification of the product to be renewed then select “Automatic Renewal Registration for Regular CPR & PCPR” or “Automatic Renewal Registration for CLIDP” whichever is applicable.		None	0	Applicant
1.3.Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None	0	Applicant
1.4.Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None	0	Applicant

1.5.After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1.Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None	0	CDRR Pre-assessor
2.1.Print the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Applicant
2.2.Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal).	2.1.FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF	0	FDA Cashier

	2.2 Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None	1 working day	FDA Cashier
3.Receives acknowledgement receipt through email	3.1 The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to QA.	None	9 working days	CDRR Evaluator
	3.2 QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	5 working days	FDRO IV (Supervisor)

	3.3 Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/ Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	5 working days	CDRR Director
4. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	Applicant
	TOTAL:		20. **Working days**	

22.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PHARMACEUTICAL PRODUCTS (NEW CHEMICAL ENTITIES/MONITORED RELEASE)

This Certificate of Product Registration is granted to Marketing Authorization Holders of chemical or synthetic drug products classified under Monitored Release either as a New Drug/New Chemical Entity or a pharmaceutical/therapeutic innovation of a Tried and Tested/Established Drug (i.e., involving use for a new indication, a new mode of administration, a new dosage form, and/or a new fixed-dose combination of two or more active ingredients) upon compliance to the agency-prescribed Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION	
ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier	 Applicant Company/Manufacturer (For the whole Part I)

Table of Contents Sec. C Guidance on the Administrative Data and Product Information Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary	FDA Website & Cashier

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3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports	

1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	

Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	2.2 Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	20 working days	CDRR-CRR Unit Personnel
	2.4 Decks/Assigns the application to the assigned evaluators of Registration Section and Clinical Research Section.	None	1 working day	CDRR Director
	2.5 Evaluates the application according to requirements and prescribed standards	None	51 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)/ Medical Specialist II

3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	a. Clinical Research Section (Safety and Efficacy evaluator) 3.1 Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) 3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III/ Medical Specialist II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	40 working days	FDRO III

	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for the approval of the application	None	1 working day	FDRO I/II
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day (per batch of applications)	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).		TOTAL:	120 working days	

RENEWAL & POST-APPROVAL CHANGES (PAC)

23.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF REPRODUCTIVE HEALTH (RH) PRODUCTS (AUTOMATIC RENEWAL) [MANUAL SUBMISSION]

This Certificate of Product Registration is granted by the FDA to the Marketing Authorization Holder in order to continue marketing a specific product in the country provided that the conditions for Automatic Renewal stipulated in Book II Article 1 Section 3.B (2) of the IRR of RA 9711 have been fulfilled.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Reproductive Health Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 and AO No.-2005-0031 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF

CKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR ELIGIBILITY TO AUTOMATIC RENEWAL REGISTRATION Implementing Rules and Regulations (IRR) of Republic Act No. 9711 There shall be automatic renewal of the CPR when the following conditions are satisfied: 1.The application is filed before the expiration date of the registration; 2.The prescribed renewal fee is paid upon filing of the application; and 3. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secures 14-digit Document Tracking Number (DTN) and schedule of appointment/submission to FDAC.	1. Sends the Document Tracking Log (DTL) bearing the DTN and schedule of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3. For accepted applications, pays the required fee through any of the following: • BANCNET •Landbank OnColl •Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit *Personnel*
	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*/ CRR *Personnel*

	3.4 Evaluates the application according to requirements and prescribed standards	None	9 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.5 Prepares draft Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares draft Letter of Disapproval (LOD) when the application does not merit an Approval recommendation	None	1 working day	*FDRO I/II*
	3.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	3 working days	*FDRO III*
	3.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None		*FDRO II*
	3.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*FDRO III*
	3.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*

	3.10 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	3.11 Recommends the final decision by affixing signature when approval of the application is recommended.	None	1 working day (per batch of applications)	*CDRR Director*
	3.12 Signs and approves the final decision	None	1 working day (per batch of applications)	FDA *Director General*
	3.13 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	3.14 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
	TOTAL:		**20 WORKING DAYS**	

24.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR REPRODUCTIVE HEALTH PRODUCTS (NEW CHEMICAL ENTITIES AND INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of reproductive health products upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 **Initial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF **Unbranded:** Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF **New Drug/Monitored Release:** Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF

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Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
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6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses	

5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References	
Additional Requirements: 1. Risk Management Plan – which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) 2. MRE to Initial: Periodic Safety Update Report (PSUR), or proof of prior submission 3. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] 4. Scientific Evidence/s (*including but not limited to meta analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international organizations*) on the Non-Abortifacient Property based on the indication/use, at the dose/usage of the product*** Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions • Petitions, Position papers and/or Scientific Evidence on the Non-Abortifacient Property of the drug product from interested parties (if available) ***As per Revised Implementing Rules and Regulations of Republic Act No. 10354, Rule 7, Sec. 7.04 (C).	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer (FDA) Applicant Company/ Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN)	None	0	CDRR Personnel
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	.1 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank /FDAC *Personnel*
	2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators	None	20 working days	CDRR-CRR Unit Personnel

	2.4 Decks/Assigns the application to the assigned evaluator *For MR applications, simultaneous decking to registration evaluator and CRS evaluator *For Initial applications, the registration evaluator shall endorse the submitted non-abortifacient evidence to the CRS.	None	1 working day	LRD Chief
	2.5 Evaluates the application according to the requirements and prescribed standards	None	21 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 For MR applications: a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of	None		FDRO I/II/III/ Medical Specialist II/III

	Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	10 working days	FDRO III
	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 The assigned evaluator shall notify the TWG on RH product secretariat for applications which passed the QSE evaluation.	None	1 working day	FDRO I/II/TWG RH product secretariat

	3.8 Preparation of the FDA Advisory for the publication of submitted non-abortifacient evidence by the MAH/applicant as a notice for the start of submission of petitions, position papers and corresponding evidence of interested parties.		10 working days	TWG RH product secretariat
	3.9 Issues FDA Advisory on the publication of notice for the submission of petitions, position papers and corresponding evidence of interested parties.	None	10 working days	CDRR Director/Information and Communication Technology Management Division (ICTMD) Staff
4. Submits petitions, position papers and corresponding evidence from interested parties.	4.1 Receives documents related to the petitions, position papers and corresponding evidence of interested parties and forwards the aforementioned documents to the CRS and Registration Section.	None	1 working day	CRR personnel
	4.2 For new non-abortifacient evidence, forwards the endorsement letter and corresponding documents on the non-abortifacient property to the Independent Evidence Review Group (ERG) for review. For non-abortifacient evidence previously reviewed, proceed to item no. 4.4.	None	1 working day	FDRO I/II (CRS evaluator)/ Medical Specialist II/III

	4.3 Reviews and provides recommendation on whether the drug product is abortifacient or non-abortifacient, based on the submitted evidence for non-abortifacient from the applicant; petitions and/or comments from interested parties and available scientific evidence.	None	20 working days	External consultants
	4.4 Consolidates the assessment review of the ERG and prepares a summary of findings based on the submitted evidence for non-abortifacient from the applicant; petitions or comments from interested parties; and recommendations from external experts and forwards to the FDA TWG. In case of regulatory action/s with other National Regulatory Agency/ies (NRAs), conflicting evidence on non-abortifacient evidence, safety concern from the country of origin where the RH product is available or from Stringent Regulatory Agency (SRA), a Communication Letter shall be issued to the applicant company.	None	10 working days	FDRO I/II (CRS evaluator)/ Medical Specialist II/III
	4.5 Deliberates on the drug product based on the summary of findings forwarded by the CRS and makes the final recommendation and determines if the drug product is abortifacient or non-abortifacient.	None	1 working day	FDA TWG on RH products

	4.6 Drafts the resolution in accordance with the final recommendation of the TWG and forwards for review and comments of the TWG on RH Product Chairperson, Vice-Chairperson and Members.	None	1 working day	TWG RH product secretariat/ TWG RH Product Chairperson, Vice-Chairperson and Members
	4.7 Forwards the resolution to the Office of the Director General.	None	1 working day	CRR personnel
	4.8 Signs and approves the resolution. Forwards the signed copy of resolution to CDRR.	None	1 working day	Director General
	4.9 Prints the final output document (CPR) in accordance with the resolution (found that the product is non-abortifacient), affixes initial, and forwards it to the senior evaluator (FDRO III). If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR If non-compliant, prints the final output document (LOD).	None	1 working day	FDRO I/II/FDRO III
	4.10 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.11 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)

	4.12 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	4.13 Recommends the final decision by affixing signature.	None	1 working day	CDRR Director
	4.14 Signs and approves the final decision (CPR/LOD).	None	1 working day	Director General
	4.15 Forwards the signed CPR or LOD to the CDRR-CRR	None	1 working day	ODG personnel
	4.16 Encodes/Updates the database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.17 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
5. Received the CPR/LOD/Letter	5 Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13		**TOTAL:**		**120 WORKING DAYS**

25.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR VETERINARY DRUGS AND PRODUCTS [INITIAL/MONITORED RELEASE (NEW CHEMICAL ENTITIES)]

This Certificate of Product Registration is granted to Marketing Authorization Holders of veterinary drugs and products upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Veterinary Drug and Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release (New Chemical Entities): Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF VETERINARY DRUGS AND PRODUCTS 1. Notarized Integrated Application Form (in excel and in pdf format) 2. Proof of Payment	FDA Website FDA Cashier

3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/ Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company/ Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/
6. Certificate of Analysis of active Raw Material(s)	Manufacturer
a. From supplier of API	Applicant Company/
b. From manufacturer of finished product	Manufacturer
7. Technical Specifications of Finished Product	(Supplier of API & Manufacture
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/ Manufacturer
11. Stability Studies	Applicant Company/
12. Labeling Materials (facsimile labels)	Manufacturer
13. Representative Sample (upon request of the evaluator)	Applicant Company/ Manufacturer
Additional Requirements:	Applicant Company/
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	Manufacturer
2. For imported products:	Applicant Company/
a. Certificate of Pharmaceutical Product (CPP)	Manufacturer
b. Foreign GMP Clearance	Applicant Company/
3. For new veterinary drugs:	Manufacturer
a. Pre-clinical studies	Applicant Company/
b. Protocol for monitored release	Manufacturer
4. For fixed-dose combination: Rationale of the Combination	Applicant Company/
5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Manufacturer
	FDA CDRR (Applicant Compan
	Applicant Company/ Manufacturer

	Applicant Company/ Manufacturer Applicant Company/ Manufacturer FDA CDRR
References: 1. DOH AO No. 67 s. 1989 - Revised Rules and Regulations on Registration of Pharmaceutical Products 2. DOH AO No. 111-A s. 1991 – Rules and Regulations on Registration of Veterinary Drugs and Products 3. BC No. 5 s. 1997 – Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*
E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR *Personnel*

For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards (Quality)	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.6 Evaluates the application according to requirements and prescribed standards (Pre-clinical studies)	None		*FDRO III (Senior Evaluator)*

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	FDRO I/II/III
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II/III
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31.			working days	

26. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (REGULAR RENEWAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders to continue the manufacture, distribution and sale of pharmaceutical products based on compliance with quality, safety and efficacy standards.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 and AO No.-2005-0031 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF Additional (if with variation/s) Payment shall be based on FDA-Circular-No.-2014-008 , Annex D on a per product, per change basis. Surcharge (based on FDA-Circular-No.2011-004) Computation: 2 x (renewal registration fee) + 10%* (renewal registration fee) *If the renewal application is submitted on the: First month: 10% First day of the second month: 20% First day of the third month: 30% First day of the fourth month: 40% Any renewal application filed after the 4th month (120th day) shall be treated as an initial application.

CHECKLIST OF REQUIREMENTS	ERE TO SECURE
Documentary Requirements	
a. Copy of previously issued CPR	Applicant
b. Copy of LTO of manufacturer, importer, trader, and/or distributor (and renewal case number with proof of payment)	Company Applicant
Copy of Certificate of GMP Clearance for imported product (and/or initial or renewal application, whichever is applicable)	Company Applicant Company
CHECKLIST OF REQUIREMENTS FOR REGULAR RENEWAL REGISTRATION **FOR PRESCRIPTION PRODUCTS/ OVER-THE-COUNTER PREPARATIONS/ HOUSEHOLD REMEDIES** 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment . Unit Dose and Batch Formulation . Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 6. Assay and Other Test Procedures including Assay with Data Analysis 7. Stability Studies . Labeling Materials (actual/commercial label) 9. Actual commercial samples (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.) Additional Requirements: 1. Post-marketing commitments (if any) 2 . For imported products: Foreign GMP Clearance For oral solid dosage forms, proof of interchangeability (Bioequivalence study or Biowaiver, whichever is applicable)	Applicant Company/FDA Website Applicant Company Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant

FOR BIOLOGICALS/SIMILAR BIOTHERAPEUTIC PRODUCTS 1. Integrated Application Form 2. Proof of Payment 3. Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated 5.Labeling Materials (actual/commercial labels) 6.Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) 7.If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	Applicant Company/FDA Website Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant
Additional Requirements: 1. Post-marketing commitments (if any) 2. For products qualifying for Generic Labeling Exemption (GLE): Request for GLE 3. For imported products: Foreign GMP Clearance 4. Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) 5. List of Countries where the vaccine is already licensed and date of approval (for vaccines) 6. Adverse event following immunization report (Summary of Annual Reports) (for vaccines)	Applicant Company/Manufacturer Applicant Company/Manufacturer pplicant Company/Manufactur
FOR HERBAL MEDICINES/TRADITIONALLY USED HERBAL PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment 3. Unit Dose and Batch Formulation 4. Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 6. Stability Studies	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufactur

7. Labeling Materials (actual/commercial label) 8. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application)	Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: Post-marketing commitments (if any) For imported products: Foreign GMP Clearance	Applicant Company/Manufacturer
EDICAL GAS (OXYGEN) otarized Integrated Application Form (in excel and pdf format) oof of Payment Valid agreements between the manufacturer, trader, importer, distributor, where applicable Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) Certificate of Analysis issued by CIGI for the product Manufacturing Procedure, Production Equipment, Sampling, In-process controls Labeling Materials (actual/commercial label) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	 Applicant Company/Manufacturer Applicant Company/Manufacturer pplicant Company/Manufacturer Applicant Company/Manufacturer Applicant
Additional Requirements: Post-marketing commitments (if any) For imported products: Foreign GMP Clearance	Applicant Company/Manufactu Applicant Company/Manufactu
TERINARY DRUG PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format)	

2. Proof of Payment 3.Unit Dose and Batch Formulation 4.Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) Assay and Other Test Procedures including Assay with Data Analysis Stability Studies Labeling Materials (actual/commercial label) Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal:	Applicant Company Applicant Company Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
he approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.) l Requirements: Post-marketing commitments (if any)	Applicant Company/ Manufacturer

For imported products: Foreign GMP Clearance	FDA CDRR
onitored-Release Extension (MRE)	
Notarized Integrated Application Form (in excel and pdf format)	Applicant
Proof of payment	Company/ Manufacturer
Copy of Latest Certificate of Product Registration (CPR)	Applicant
Unit Dose and Batch Formulation	Company/ Manufacturer
Actual/Commercial Labeling Materials	Applicant
l Requirements:	
For MRE/MR to Initial applications, proof of approval/clearance/extension of Post-Marketing Surveillance (PMS) Report	Company/ Manufacturer
MRE to Initial: Periodic Safety Update Report (PSUR), or proof of submission	Applicant
Risk Management Plan (RMP)	Company/ Manufacturer
Periodic Safety Update Report (PSUR)	Applicant
For imported products:	Company/ Manufacturer
Certificate of Pharmaceutical Product (CPP) Foreign GMP Clearance	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3.For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*
	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit

	Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section		20 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	LRD Chief
	Evaluates the application according to requirements and prescribed standards	None	51 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and/or Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator.		1 working day	FDRO I/II/III
	4.2 If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic			

	4.3.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.4.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II
	4.5.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.6.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	4.7.Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	4.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.9.Encodes/Updates the Database and Endorses the final output document (CPR/Certificate/Letter/LOD) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	4.10.Scans, barcodes, and emails the scanned copy of the final output document (CPR/Certificate/LOD/Letter) to the client, updates the database and website, and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
5.Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

27. ISSUANCE OF CERTIFICATE OF PRODUCT REGUSTRATION FOR PHARMACEUTICAL PRODUCTS (VARIATION-TURNED-INITIAL APPLICATIONS)

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products
Fees to be Paid		Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Variation-turned-Initial: Branded: Php 15,000.00 + LRF Unbranded: Php 10,000.00 + LRF Monitored Release Status: New application: Php 33,333.33 + LRF (5-year validity); Pending application: Php 13,333.33 + LRF (paid for 3-years and will avail 5-year validity) (according to FDA Advisory No. 2021-2904) The Legal Research Fund (LRF) fee is the amount equivalent to one percent (1%) of the fee imposed but in no case lower than ten (10) pesos.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LIST OF VARIATION-TURNED-INITIAL APPLICATIONS Mav-1: Change and/or additional indication/dosing regimen/patient population/inclusion of clinical indication extending the usage of the product MaV-4: Addition or replacement of the manufacturing site of the drugs product MaV-10: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-

For modified release oral dosage forms For other critical dosage forms such as sterile preparations MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of the capsule shell for modified release dosage form MaV-12: Change in the primary packaging material for sterile drug product Qualitative and quantitative composition and/or Type of container and/or nclusion of primary packaging material MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles) MiV-PA15: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline) For other non-critical dosage forms (e.g. oral liquid, external preparation) MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)] MiV-PA28: Change in primary packaging for non-sterile drug product Qualitative and quantitative composition and/or Type of container and/or Inclusion of the primary packaging material Additional route of administration Change of manufacturing site (same subsidiary) of the drug product	Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CHECKLIST OF REQUIREMENTS FOR VARIATION-TURNED INITIAL APPLICATIONS FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products 1. Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) 2. Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) 3. Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable) No.-2014-008 Annex D	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*

E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for	None	0	CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC *Personnel*

	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR)
	Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit *Personnel*
	Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	CDRR *Director*
	Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/*
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) (from safety and efficacy evaluation, if applicable) when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			

	4.2 For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		*FDRO I/II/III*
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the Certificate	None	1 working day	*FDRO I/II*
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*

	Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*
	Scans and barcodes the final output document (CPR/LOD/Letter); emails scanned copy of the final output document to the client; and endorses the final output document (hard copy) to the AFS Releasing Section.	None	1 working day (per batch of applications)	FDA Records *Personnel*
5. Receives the CPR/ LOD letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

28. ISSUANCE OF CLEARANCE AND CERTIFICATE FOR FOREIGN DONATIONS

This certificate and clearance are issued for foreign drug donations in support of the service and programs of the health sector.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order No. 2020-0001: Revised Guidelines in the Facilitation and Management of Foreign Donations involving Health and Health-Related Products I. Criteria for Acceptable Foreign Drug Donations Listed in the Latest Edition of the Philippine National Formulary For pharmaceuticals which are not included in the Latest Edition of the Philippine National Formulary (PNF), must satisfy at least one of the following conditions: Must contain the same active ingredients, dosage form and strength as those products already approved by and registered at FDA Philippines; or Orphan drugs and drugs for compassionate use; or Critically needed drugs (Note: Subject to approval by the Secretary of Health) Must NOT be classified under the following: Experimental/investigational drugs and MR registration of FDA Philippines Regulated, prohibited and/or dangerous drugs of PDEA Must have a shelf-life of at least 12 months (or 1 year) at the expected date of arrival For pharmaceuticals with shelf life below 12 months, must satisfy at least one of the following conditions:	Applicant Company Applicant Company

The product has a total shelf-life of less than 2 years AND has a remaining of at least one-third (1/3) of its shelf-life. Recommended as suitable for distribution as per case assessment by the DOH/TWG and approved by the Secretary of Health despite the limited product shelf-life remaining	
II. Requirements	
II-A. Administrative Data	
Endorsement Letter from the Bureau of International Health Cooperation (BIHC) – DOH	BIHC – DOH
Letter of intent to donate	Applicant Company
Authenticated Deed of Donation (Philippine Embassy/Philippine Consulate)	Philippine Embassy/Philippine Consulate
Letter of Concurrence or Acceptance	Applicant Company
List of all drug products to be donated with the following information: International Nonproprietary Name (INN) or Generic name Brand name (if any) Dosage Form and Strength Batch/Lot Number Expiration Date Total quantity of batch/lot of products to be donated	Applicant Company
Certificate of no commercial use and given for free or Notarized Affidavit of Undertaking indicating “not for commercial distribution or sale” duly signed by the recipient/consignee	Applicant Company
Distribution plan/ Allocation list of intended beneficiaries	
Photocopy of shipping documents such as bill of lading airway bill, commercial invoice, and packing list	
8. Copy of Post donation report (where applicable)	
9. Proof of payment (PHP 510.00)]	Applicant Company
II-B. Quality	Applicant Company
Certificate of Pharmaceutical Product (CPP)	Applicant Company
For countries not issuing CPP, the following shall be submitted: Current Good Manufacturing Practice (CGMP) Certificate issued by the drug regulatory authority of the product’s country of origin	Applicant Company
Certificate of Free Sale (CFS) authenticated by the territorial Philippine Consulate	Applicant Company

Certificate of Analysis (CoA) per batch/lot of products Complete labelling materials, i.e., primary and secondary packaging, and package insert, which must contain texts in English/English translation of ALL of the following mandatory information: International Nonproprietary Name (INN) or Generic name Brand name (if any) Dosage Form and Strength Mode of Administration Batch/Lot Number Expiration Date Formulation Storage conditions	Applicant Company Applicant Company

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**CESSING TIME**	**PERSON RESPONSIBLE**
Secure a schedule of appointment / submission to FDAC	Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2.E-mail submission: Submits the application for pre- assessment through fdac.letters.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre- assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		Center for Drug Regulation and Research Personnel/ FDAC personnel

For accepted applications, pays the required fee through any of the following:BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	Verifies and posts the payment through updating the FDA FIS. FDA personnel forwards the application with proof of payment to CDRR.	ee Table Above		Administrative Finance Service (AFS) Staff/Cashier
	. Receives the application from FDAC and encodes/updates the database	None	1 working day	CDRR- Central Receiving and Releasing (CRR) unit
	2 Decks/Assigns the application to the assigned evaluator	None	1 working day	*LRD Chief/ CRR Unit Personnel*
	3 Evaluates the application according to requirements and prescribed standards	None	1 working day	*Food-Drug Regulation Officer (FDRO) I/II*

4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares the worksheet and draft Clearance Letter/Certificate of Foreign Donated Product Registration issuance upon approval of the recommendation Prepares the worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1-11 working days varies depending on the value of the received requests and the total number of batches/lots of products to be donated)	*FDRO I/II*
	2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	1 working day	*FDRO III*
	3 Prepares the final output document (Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	depending on the value of the received requests and the total number of batches/lots of products to be donated)	*FDRO II*
	4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None		*FDRO IV (Supervisor)*
	Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
Receives the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval	eleases the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval to the client	None	1 working day	*AFS Releasing Section Personnel*
	TOTAL:	**PHP510.00**	**20 working days**	

29. ISSUANCE OF CLINICAL TRIAL AMENDMENT APPROVAL UNDER REGULATORY RELIANCE

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO -2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment	Applicant Company
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff
. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	2.1 Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 Php 1,000.00 + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff

3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	10 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2 Assignment of Scientific Advisory Committee (SAC) **The decision to assign to SAC is based upon the complexity of the amendments.*	None	1 working day	FDRO I/II/III
	3.3 SAC Review	None	9 working days	Scientific Advisory Committee (SAC)
	3.4 Reviews the evaluated application bearing the recommendation of the evaluator.	None	2 working days	Clinical Research Section Supervisor
	3.5 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD)	None	1 working day	PRSDD Chief
	3.6 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	3.7 Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
. Receives the letter	4. Releases the letter to the client	None	1 working day (per batch of applications)	FDAC Releasing Section Personnel
	TOTAL:	**PHP 1,010.00**	**15 Working Days**	

30. ISSUANCE OF CLINICAL TRIAL AMENDMENT APPROVAL UNDER REGULATORY RELIANCE

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO -2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment	Applicant Company
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff
. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	1. Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 Php 1,000.00 + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff

3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	10 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2 Assignment of Scientific Advisory Committee (SAC) **The decision to assign to SAC is based upon the complexity of the amendments.*	None	1 working day	FDRO I/II/III
	SAC Review	None	9 working days	Scientific Advisory Committee (SAC)
	Reviews the evaluated application bearing the recommendation of the evaluator.	None	2 working days	Clinical Research Section Supervisor
	Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD)	None	1 working day	PRSDD Chief
	Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
. Receives the letter	Releases the letter to the client	None	1 working day (per batch of applications)	FDAC Releasing Section Personnel
	TOTAL:	**PHP 1,010.00**	**15 Working Days**	

31. ISSUANCE OF INITIAL CLINICAL TRIAL APPROVAL (CTA) AND IMPORT LICENSE APPROVAL (ILA)

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	Administrative Order No.-50-2001 & FDA Circular No.2012-007-A FDA Review: Php 2,500.00 + 1% LRF Fee External Regulatory Reviewers: Php 60,000.00 Importation Clearance for Clinical Study: Php 500.00/importation + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

AO 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products **Initial Clinical Trial & Import License Application Requirements** 1. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application Form 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site 10. Informed Consent Form/Assent Form 11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance 14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product 16. Acknowledgement Receipt/Approval of the Research Ethics Committee (REC)	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. ay for the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Then send the proof of payment to the FDAC.	Receives the payment from the applicant for posting 2.2 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	***Timeline starts after posting of payment**	FDA Cashier/ Landbank FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff

	2.5 Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (7 calendar days to respond to the queries)	None	2 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	2.6 If the application is deemed complete, assign a regulatory reviewer and issue regulatory review permit to the applicant.	None	1 working day	*FDRO I/II/III*
Submit the following document to the assigned external regulatory reviewer and pay for the review fee: • Cover Letter • Clinical Trial Protocol • Informed Consent Form/Assent Form • Investigator's Brochure • GCP Certificate and Curriculum Vitae of the PI of each site • Investigational Product Information Submit the Acknowledgement Receipt of the Regulatory Reviewer within three (3) calendar days after the receipt of the Regulatory Reviewer 3.3. Submit the Proof of Payment to the Regulatory Reviewer within 14 calendar days	3. Reviews Pharmaceutical data requirements and Import License application	See Table Above	30 working days	*FDRO I/II/III*

4. *If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator	4.1. Assesses the application through the FDA CT Assessment Form, then forward the assessment to CRS though email. *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (30 calendar days to respond to the queries) *This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6 and FDA Circular No. 2020-0029-1)		30 working days	*External Regulatory reviewer [St. Luke's Medical Center (SLMC), University of the Philippines – National Institutes of Health (UP-NIH), Philippine Heart Center (PHC)]*
	4.2 Reviews the assessment from the Regulatory reviewer	None	2 working days	*FDRO I/II/III*
	4.3 Reviews the evaluated application bearing the recommendation of the evaluator	None	1 working day	*Clinical Research Section Supervisor*
	4.4 Prints the final response and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*

	4.5 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*PRSDD Chief*
	4.6 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.7 Scans the document with decision and email to the applicant 4.8 Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
5. Receives the documents	5. Releases the appropriate CT response and IL to the client	None	1 working day	*AFS Releasing Section Personnel*
TOTAL: Service is covered under Administrative Order 2020-0010.		**PHP 63,035.00**	**40 Working days**	

32. ISSUANCE OF COMPASSIONATE SPECIAL PERMIT (CSP) OF PHARMACEUTICAL PRODUCTS [MANUAL SUBMISSION]

The CSP is granted to an institution and/ or physician the privilege to avail an unregistered or investigational drug product through a licensed importer for a certain patient suffering from a condition, with specific volume and period of use.

Center/Office/Division	:	enter for Drug Regulation and Research
Classification	:	imple
Type of Transaction	:	2B – Government-to-Businesses
Who May Avail	:	Patients, Doctors, Specialized Institutions, Specialized Society, Hospitals, Importers of Pharmaceutical Products
s to be Paid	:	Name Patient: Php 500.00/patient + 1% LRF Institutional Use: Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

CHECKLIST OF REQUIREMENTS FOR CSP Name Patient 1. Letter of Application Should include the following: a. name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)] b. name and age of the patient with a brief medical history c. itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength (Registered from country of origin) d. an estimated quantity/ volume needed/prescribed by doctor e. A written commitment on the part of all the authorized specialists to submit a Clinical Report for every patient given the product describing the quantity administered/ use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society through the importer for FDA Philippines f. A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society. Proof of Payment per patient (P500 + LRF) Names and addresses of the specialists qualified and authorized to use the product Curriculum vitae of the prescribing doctor Medical Abstract of Patient Prescription Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	 Applicant Company Applicant Company Applicant Company Applicant Company Applicant Company/Authorized Specialists Applicant Company Applicant Company Applicant Company Prescribing Doctor Prescribing Doctor Prescribing Doctor
Institutional Use 1. Letter of Application Should include the following: a. name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]	 Applicant Company Applicant Company

b. itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength (Registered from country of origin) c.an estimated quantity/ volume needed c. A written commitment on the part of all the authorized specialists to submit a Clinical Report for every patient given the product describing the quantity administered/ use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society through the importer for FDA Philippines d. A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society. 2. Proof of Payment per product (P500 + LRF) 3. Reports as prerequisites of renewal of permit a. Reconciliation of number/volume of products requested and number used and the corresponding patients b. Additional product details – name and address of manufacturer, batch/lot number, expiry date Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	Applicant Company Applicant Company/Authorized Specialist Applicant Company Applicant Company Applicant Company Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC thru fdac.letters@fda.gov.ph	2.1 Endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	2.2 Endorses the received application to the Center (applications which satisfactorily passed the pre-assessment).	None		FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*
	2.5 Evaluates the application according to requirements and prescribed standards	None	1 working day	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior Evaluator)*
	2.6 Reviews the evaluated application bearing the recommendation of the Evaluator	None	1 working day	Clinical Research Section *Supervisor*

	2.7 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*
	2.8 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD *Chief*
	2.9 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR *Director*
	2.10 Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the permit or final response	3. Releases the permit or final response to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	Php 510	**3 Working days**	

33. ISSUANCE OF ELECTRONIC CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCTS (E-CLIDP)

The CLIDP is granted to identical drug products as proof that its pharmaceutical product has been officially listed by FDA as identical, in terms of its manufacturer and formulation, to the pharmaceutical product already covered by the Principal CPR.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 and AO No.-2005-0031 Branded: Php 3,000.00/year* + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year* + 1% LRF *per year – depending on the remaining validity of the Principal Certificate of Product Registration (PCPR)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Certificate of Listing of Identical Product (CLIDP)	
1. Proof of payment	Applicant
2. Copy of the current and valid LTO of the PCPR and Identical Drug Applicant	Applicant
3. Copy of current and valid PCPR	Applicant
4. Authenticated copy of the duly notarized Distributorship Agreement, license Agreement, or other written contract between the principal CPR holder and the identical Drug Applicant	Applicant
5. Facsimile of Labeling Materials	Applicant
6. Additional Requirement for Imported Products: Foreign GMP Clearance	Applicant

References: 1. Republic Act 9711 – Food and Drug Administration Act of 2009 Administrative Order No.-2005-0031 - Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation Bureau Circular No. 11 s. 2006 - Specific Operational Instructions Implementing Administrative Order No.-2005-0031 dated December 7, 2005, Subject: Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation FDA Advisory No.2021-1791 – Pilot Implementation of the Food and Drug Administration (FDA) eService Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications FDA Advisory No.2022-0418 - Implementation of The Food and Drug Administration (FDA) Eservices Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications FDA Advisory No.2022-0907 - Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) "Applications"	1. Assess the completeness of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification.	None	0	
2. Select "Certificate of Product Registration" and select "Drug". Select the classification of the product to be registered then select "Certificate of Listing of Identical Drug Products (CLIDP) Of Pharmaceutical Products".	If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the	None	0	

3. Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application	eServices to the email address of the applicant.	None	0	
4. Fill out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None	0	
5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)		None	0	CDRR Pre-assesor
6. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail address Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	6. Post payment in eServices for confirmed payments. Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application. This will prompt automatic decking of application to respective Center	Branded: Php 3,000.00/year + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF *per year – depending on the remaining validity of the Principal Certificate of Product Registration (PCPR)	0	FDA Cashier

7. Receives acknowledgement receipt through email Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator.	7.1 The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance (QA). Note: (1) For applications with proposed brand names, request approval from the Brand Name Clearance (BNC) evaluator. (2) Any minor deficiencies/ clarifications will be communicated through electronic communication. The Client is given 5 working days to comply. If the client complies or when there is no deficiency found, the CDRR evaluator will resume its evaluation.	None	Day 1-20 20 working days	FDRO I/II (CDRR Evaluator)
	7.2 QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	5 working days	FDRO IV (CDRR Supervisor)
	7.3 Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	5 working days	Director IV

8. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	
		Total:	**30 working days**	

34. ISSUANCE OF ELECTRONIC COMPASSIONATE SPECIAL PERMIT (eCSP) OF PHARMACEUTICAL PRODUCTS

The CSP is granted to an institution and/ or physician the privilege to avail an unregistered or investigational drug product through a licensed importer for a certain patient suffering from a condition, with specific volume and period of use.

Center/Office/Division	:	enter for Drug Regulation and Research
Classification	:	imple
Type of Transaction	:	2B – Government-to-Businesses
Who May Avail	:	Patients, Doctors, Specialized Institutions, Specialized Societies, Hospitals, Department of Health, and Importers of Pharmaceutical Products
Fees to be Paid	:	Named Patient: Php 500.00/patient + 1% LRF Institutional Use: Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR CSP Basic Requirements based on the FDA Advisory No.2021-0842: Named Patient Use: 1. Accomplished e-Application Form as prescribed by FDA regulations. 2. Curriculum vitae of the Prescribing Doctor 3. Medical Abstract of the Patient 4. Medical Prescription 5. Proof of Payment Institutional Use: 1. Accomplished e-Application Form as prescribed by FDA regulations. 2. Rationale for the Volume Requested 3. Proof of other National Regulatory Authority (NRA) approval	 FDA eServices (www.fda.gov.ph) Applicant

4. Distribution Agreement 5. Clinical Study Report (if applicable) 6. Proof of Payment	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Access the online application portal through (http://eservices.fda.gov.ph) "Applications"		None		
1.2. Select the "Compassionate Special Permit" and the type of application (Named Patient Use or Institutional Use), then proceed to New Application		None		
1.3. Click "I have read and accepted the terms and conditions stated on this form". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None		
1.4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None		

1.5.	After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given.	1. Pre-assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the client thru the eService and Email notification. If incomplete, the application will not be received and will be returned to the client. Notice of deficiency will be given to the client thru eServices and Email notification.	None		FDA Evaluator (CRS Staff)
2.1.	Print the Order of Payment form with Reference Number sent through the declared e-mail address		None		
2.2.	Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal). Then, email a copy of the proof of payment to clinicalresearch@fda.gov.ph cashierposting@fda.gov.ph and cashierposting2@fda.gov.ph	2.1 FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Php 510		FDA Cashier/CRS Staff

	2.2. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier/CRS Staff
3. Receives acknowledgement receipt through email	3.1. Evaluates, Checks and quality assurance of the information and documents provided	None	3 working days	CRS Staff/ PRSDD Chief
	3.2. Approval of CSP If application is disapproved, notifies the applicant through email and will receive the Letter of Denial	None		CDRR Director
4. Receives notification and link of CSP for printing.				
	TOTAL:		**3 Working days**	

35. ISSUANCE OF ELECTRONIC PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION (e-PCPR) CONVERSION FOR PHARMACEUTICAL PRODUCTS

This Certificate of Product Registration is granted to Marketing Authorization Holders for the conversion from Regular CPR [DR-XY] to a Principal Certificate of Product Registration (PCPR) [DRP].

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products with a valid regular CPR
Fees to be Paid	:	AO No.-50-2001 and AO No.-2005-0031 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
Checklist of Requirements for Principal Certificate of Product Registration (PCPR) Conversion	
1. Copy of current and valid CPR 2. Copies of the respective current and valid License to Operate (LTO) of the principal CPR applicant and toll manufacturer (if applicable) 3. Proof of payment	Applicant Applicant Cashier

References:	
1. Republic Act 9711 – Food and Drug Administration Act of 2009 2. A.O No.-2005-0031 – Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation. 3. FDA-Advisory-No.2021-1790 – Guidelines on Principal Certificate of Product Registration Conversion Application using e-Services Portal System. 4. FDA-Advisory-No.2022-0417 – Implementation of The Food and Drug Administration (FDA) e-Services Portal System for Principal Certificate of Product Registration (PCPR) Conversion Applications for Drug Products 5. FDA-Advisory-No.2022-0907 – Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	)CESSING TIME	PERSON RESPONSIBLE
1.1. Access the online application portal through (http://eservices.fda.gov.ph) “Applications“		None		
1.2. Select “Certificate of Product Registration” and select “Drug”. Select the Product Category, Click on the Principal Certificate of Product Registration (PCPR) Conversion		None		
1.3. Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None		

1.4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None		
1.5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1. Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None		CDRR Pre-assessor
2. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail address		None		
3. Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	3.1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for sbank payments;	Php 500.00 + 1% LRF		FDA Cashier

	3.2. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier
	c. This will prompt automatic decking of application to respective Center	None		ICTMD (eService)
4. Receives acknowledgement receipt through email	4.1. The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance. *Any minor deficiencies/clarification will be communicated to the clients through electronic communication (e-NOD).	None	5 working days	CDRR Evaluator

	4.2. QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	3 working days	CDRR Supervisor
	4.3. Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	2 working days	CDRR Director
5. Receive notification and link of CPR/Letter of Disapproval for printing. Note: Once approved, applicants are required to surrender the original copy of the Certificate of Product Registration (CPR) within 3 working days.		None	0	
	TOTAL:		10. **Working days**	

36. ISSUANCE OF FOREIGN GOOD MANUFACTURING PRACTICE (GMP) CLEARANCE (DESKTOP EVALUATION) [FOR NON-PIC/S-MEMBER COUNTRIES]

This Clearance is issued to Drug Importers to assure GMP compliance of their Foreign Drug Manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP Inspection, as appropriate. This is a requirement for product registration.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Importers of Pharmaceutical Products
Fees t o be Paid	:	FDA-Circular-No.-2014-016 Initial Application of GMP Clearance Php 5,000.00 (per importer per manufacturer per site) + 1% LRF + Php 5,000.00 (FGC Unit review) + 1% LRF Renewal: Php 2,000.00 + 1% LRF Re-issuance of GMP Clearance: Php 1,000.00 + 1% LRF If recommended for Foreign Drug Manufacturer GMP Inspection Application Fee for inspection: Php 3,000.00 + 1% LRF (per application per importer per site) Inspector's Fees ASEAN: US$ 3,500.00 + UNDP-DSA* Asia Pacific: US$ 7,000.00 + UNDP-DSA* Others: US$ 10,500.00 + UNDP-DSA* Accommodations, travel, translator (if necessary), and other incurred fees: Shall be accomplished by importer(s) * UNDP-DSA is per inspector; the fixed fee is per inspection

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

GENERAL REQUIREMENTS DURING FILING AND RECEIVING OF APPLICATIONS AT THE FOOD AND DRUG ACTION CENTER (FDAC) [as per FDA-Circular-No.-2014-003]: 1. Complete application documentary requirements in a preferred document format stored in USB device (see complete list of requirements below). 2. Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier by the Central Receiving for endorsement to Accounting	FDA Website/Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks
CHECKLIST OF REQUIREMENTS FOR FGMP CLEARANCE APPLICATIONS 1. Foreign GMP Evidence Evaluation ○ Letter of Request ○ Annex B ○ Annex E ○ GMP Evidence ○ Annex C (for Non-PIC/S countries) 2. Foreign GMP Inspection ○ Letter of Request	Applicant Company Applicant Company

• Annex C • Notice of Foreign Inspection • Annex D 3. Renewal of GMP Clearance ○ Letter of Request ○ Annex B ○ Annex E ○ GMP Evidence ○ Copy of GMP Clearance previously issued ○ Annex C (for Non-PIC/S countries) 4. Proof of payment (based on FDA-Circular-No.-2014-016)	Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph on the assigned submission date as per FDA-Circular-No.-2020-026, Annex A.	1.1 Pre-assesses the completeness of the application.			FDAC *Personnel*

	1.2 Releases the result of the pre-assessment If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
.	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator	None	1working day	CDRR Director/ CRR Unit Personnel

.	2.4 Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 When the approval of the application is recommended, prepares certification. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). When the application is recommended for foreign inspection, prepare a Notice of Inspection. **Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries)*	None	1 working day	FDRO I/II/III
	3.2 Encodes and prints the appropriate document for issuance	None	1 working day	FDRO I/II/III
	3.3 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO III
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	3.6 Encodes/Updates the Database and Endorses the final output document to the ICTMD (for Certification/ Extension of Validity)/ or Releasing Section (for Notice of Inspection/LOD) *Aside from the hard copy, Notice for Inspection will also be e-mailed to the client	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.7 Scans the Releases the Certification/ Extension of validity and updates the database and website	None	1 working day (per batch of applications)	AFS-Records Personnel
4. Receives the Certification/ Notice of Inspection/LOD/Extension of Validity	4. Releases the Certification/Notice of Inspection/LOD/ Extension of Validity to the client *This excludes the application for Foreign GMP Inspection and the inspection proper. The applicant is given 90 working days upon receipt of Notice for Inspection to apply for Foreign GMP Inspection	None	1 working day	FDAC Releasing Section Personnel
5. Endorse Recommendation with complete documents and requirements *Recommendation after on-site inspection	5.1 Accepts the endorsement with complete documents and requirements and encodes/updates the database	None	1 working day	Field Regulatory Operations Office and Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit Personnel
	5.2 Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director/ CRR Unit Personnel

	5.3 Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	5.4 When the approval of the application is recommended, prepares certification. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). *Any clarifications will be communicated to Drug GMP Inspectorate Task Force	None	1 working day	FDRO I/II/III
	5.5 Encodes and prints the appropriate document for issuance	None	1 working day	FDRO I/II/III
	5.6 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO III
	5.7 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	5.8 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
.	5.9 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	5.10 Scans and Endorses the Certification/LOD to AFS-Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

6. Receives the Certification/LOD	6. Releases the Certification/LOD	None	1 working day	AFS Releasing Section Personnel
TOTAL: Service is covered under Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 120 working days was proposed.			120 working days	

37. ISSUANCE OF FOREIGN GOOD MANUFACTURING PRACTICE (GMP) COMPLIANCE (DESKTOP EVALUATION) [FOR PIC/S-MEMBER COUNTRIES]

This Clearance is issued to Drug Importers to assure GMP compliance of their Foreign Drug Manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP Inspection, as appropriate. This is a requirement for product registration.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Importers of Pharmaceutical Products
Fees to be Paid	:	FDA-Circular-No.-2014-016 Initial Application of GMP Clearance Php 5,000.00 (per importer per manufacturer per site) + 1% LRF + Php 5,000.00 (FGC Unit review) + 1% LRF Renewal: Php 2,000.00 + 1% LRF Re-issuance of GMP Clearance: Php 1,000.00 + 1% LRF If recommended for Foreign Drug Manufacturer GMP Inspection Application Fee for inspection: Php 3,000.00 + 1% LRF (per application per importer per site) Inspector's Fees ASEAN: US$ 3,500.00 + UNDP-DSA* Asia Pacific: US$ 7,000.00 + UNDP-DSA* Others: US$ 10,500.00 + UNDP-DSA* Accommodations, travel, translator (if necessary), and other incurred fees: Shall be accomplished by importer(s) * UNDP-DSA is per inspector; the fixed fee is per inspection

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

GENERAL REQUIREMENTS DURING FILING AND RECEIVING OF APPLICATIONS AT THE FOOD AND DRUG ACTION CENTER (FDAC) [as per FDA-Circular-No.-2014-003]: Complete application documentary requirements in a preferred document format stored in USB device (see complete list of requirements below). Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier - One copy of the OnColl payment slip will be collected by the Central Receiving for endorsement to Accounting.	FDA Website/ Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks
CHECKLIST OF REQUIREMENTS FOR FGMP CLEARANCE APPLICATIONS 1. Foreign GMP Evidence Evaluation Letter of Request Annex B Annex E GMP Evidence 2. Foreign GMP Inspection Letter of Request Annex C Notice of Foreign Inspection Annex D 3. Renewal of GMP Clearance Letter of Request Annex B Annex E GMP Evidence Copy of GMP Clearance previously issued	Applicant Company Applicant Company Applicant Company

4. Proof of payment (based on FDA-Circular-No.-2014-016)	FDA Cashier/Other FDA-Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph on the assigned submission date as per FDA-Circular-No.-2020-026, Annex A.	1.1 Pre-assesses the completeness of the application.			FDAC *Personnel*
	1.2 Releases the result of the pre-assessment If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following:	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank

• BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.				FDAC *Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director/ CRR Unit *Personnel*
	2.4 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 When the approval of the application is recommended, prepares certification approval. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). When the application is recommended for foreign inspection, prepare a Notice of Inspection.	None	1 working day	*FDRO I/II/III*

	*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	3.2 Encodes and prints the appropriate document for issuance	None	1 working day	*FDRO I/II/III*
	3.3 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO III*
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	3.6 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	3.7 Scans and Endorses the Certification / Extension of Validity and updates the database and website	None	1 working day (per batch of applications)	FDA Records *Personnel*
4. Receives the Certification / Notice of Inspection/LOD/ Extension of Validity	4. Releases the Certification/ Notice of Inspection/LOD/ Extension of Validity to the client	None	1 working day	*AFS - Releasing Section Personnel*
Service is covered Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 60 working days was proposed.		**TOTAL:**	**60 working days**	

38. ISSUANCE OF IMPORT LICENSE AMENDMENT

The IL Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the initial IL issued in terms of its validity (two-year extension of the validity of the IL is issued upon submission of an application within 120 calendar days prior to the expiration of the validity of the Initial IL) and request of additional quantity, or update of information of investigational drug products and ancillary supplies needed for the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsor, Contract Research Organizations, Importer, and Principal Investigator
Fees to be Paid	:	AO No.-50-2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Import License Amendment (Extension of Validity and Addition of Quantity/Item) 1.Cover Letter (FDA-CRS Form 2.0) 2. Investigational Product Information (FDA-CRS Form 4.0) 3. Import License Application Form (FDA-CRS Form 5.0) 4. Rationale for the request and/or supporting data 5. Proof of payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Sends an application e-mail containing the requirements to fdac.letters.cdrr@fda.gov.ph	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement e-mail with the order of payment to the applicant	None		*FDAC Personnel*
2. Pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to the FDAC.	2.1 Receives the payment from the applicant for posting. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		*FDA Cashier/Landbank* *FDAC Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	*Center for Drug Regulation and Research (CDRR)* – *Central Receiving and Releasing (CRR) Unit Personnel*
	2.3 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (clock stops) *The applicant is expected to respond to the query/queries within seven (7) calendar days. If no response is received from the applicant within the required period, the application shall be disapproved.	None	13 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	2 working days	Clinical Research Section Supervisor
	3.3 Prints the final response and transmittal, and forwards the application to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.6 Scans the document with decision and email to the applicant 3.7 Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel

4. Receives the letter	4. Releases the IL Amendment response to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	**PHP 510.00**	**20 working days**	

39. PROCESSING OF IMPORT LICENSE NOTIFICATION

The IL Notification is submitted by the Sponsor or Clinical Research Organization quarterly of every shipment of investigational drug products and ancillary supplies entering the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All licensed establishments
Fees to be Paid	:	AO 50 s. 2001, FDA Circular 2012-007-A Php 500.00 + 1% LRF per shipment

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products	
Import License Notification Requirements	
. Cover Letter (FDA-CRS Form 2.0)	Applicant Company
. Proof of Payment	Applicant Company
. Investigational Product Importation Report (FDA-CRS Form 9.0, Appendix D3	Applicant Company
. Ancillary Supplies Importation Report (FDA-CRS Form 10.0, Appendix D4), if applicable	Applicant Company
. Copy of Proforma Invoice/s	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Sends an application e-mail containing the requirements to fdac.letters.cdrr@fda.gov.ph	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement e-mail with the order of payment to the applicant	None		*FDAC Personnel*

2. Pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above		*FDA Cashier/ Landbank FDAC Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	*Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit*
	2.3 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*
	2.4 Evaluates the application according to requirements and prescribed standards	None	1 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	2.5 Encodes/Updates the Import License Database	None	1 working days	*FDRO I/II/III Evaluator)*
	TOTAL:	**PHP 510.00/ shipment**	**3 working days**	

40 . ISSUANCE OF INITIAL CLINICAL TRIAL APPROVAL (CTA) AND IMPORT LICENSE APPROVAL (ILA) UNDER REGULATORY RELIANCE

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial. The Philippine FDA recognizes the other National Regulatory Authority decision in the issuance of CT approval based on the criteria set under FDA Circular 2023-004.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 & FDA Circular No.2012-007-A : Php 2,500.00 + 1% LRF Fee for External Regulatory Reviewers: Php 60,000.00 Import License for Clinical Study: Php 500.00/importation + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
AO 2020-0010 : Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site	Applicant Company

10. Informed Consent Form/Assent Form 11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance 14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product	
Additional requirements based on FDA Circular No.2023-004 16. A formal letter written request from the applicant notifying the FDA of its intent to avail of the abridged review, identifying the RDRA. 17. Copy of the clinical trial approval or any equivalent from the identified RDRA. Proof of conduct of the clinical trial in the country of RDRA such as clinical trial registry. 18. A Sworn Assurance duly signed by the Sponsor or the authorized CRO stating the requirements under Section V.A.7.b and A.7.c of the Circular	
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff

For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	1 Upon receipt of the proof of payment, the application will be encoded/update in the database.	Php 2,500.00 + 1% LRF Import License for Clinical Study: Php 500.00/importation + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2.2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff
	2.3 Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (3 working days to respond to the queries)	None	1 working day	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2.4 If the application is deemed complete, assign a regulatory reviewer and issue regulatory review permit to the applicant.	None	1 working day	FDRO I/II/III
	2.5 Reviews Pharmaceutical data requirements and Import License application	None	15 working days	FDRO I/II/III

3. If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator.	3. Assesses the application though the FDA CT Assessment Form *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (10 calendar days to respond to the queries)	Fee for External Regulatory Reviewers: Php 60,000.00 (direct to External reviewers) FDA Circular 2012-007-A	15 working days	External Regulatory reviewer *[St. Luke's Medical Center (SLMC), University of the Philippines – National Institutes of Health (UP-NIH), Philippine Heart Center (PHC)]*
	*This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6)			
	3.1 Reviews the assessment from the Regulatory Reviewer	None	1 working day	FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	1 working day	Clinical Research Section Supervisor
	3.4 Prints the final response and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	3.5 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief

	3.6 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.7 Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
4. Receives the approval	4. Releases the appropriate CT response and IL to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	**PHP 63,035.00**	**20 Working days**	

41. ISSUANCE OF POST-MARKETING SURVEILLANCE (PHASE IV Clinical Study) Application Approval [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020]

This Approval of Post-Marketing Surveillance (Phase IV Clinical Study) Application is issued to applicants as part of the post-approval requirements in the issuance of a Certificate of Product Registration for Monitored-Release/New Chemical Entities applications if additional activity(ies) are necessary based on FDA-Circular-No.2021-020.

Center/Office/Division	:	l Regulation and Research
Classification	:	al
Type of Transaction	:	nent-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), and Importers of Pharmaceutical Products Note: This is only applicable if additional PV activity(ies) are determined to be necessary by FDA based on FDA-Circular-No.2021-020
Fees to be Paid	:	nistrative-Order-No.-50-2001 Protocol for MR/Post Marketing Surveillance: Php 2,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

Time schedule or duration of clinical trial. Duties and responsibilities of research personnel. a. The investigator must conduct the studies in conformance with the “Declaration of Helsinki” or the laws and regulations of the country in which the research is conducted, whichever represent the greater protection of the individual b. The investigator must keep careful records of his study and retain them for at least two years after the new drug application is approved. The records must be available promptly to the drug sponsor (usually the drug manufacturer) and to the drug regulatory agency. Progress reports must be sent to the sponsor at intervals not exceeding one year. c. The investigator must send emergency reports to the sponsor and the regulatory agency when dangerous adverse effects are observed. d. The investigators must observe the regulations regarding consent of human subjects being given an investigational drug. Bibliography List of Hospital Resources/Personnel Required. List of Basic Sciences Resources Appendices including informed consent form, patient/case report form, flowchart of activities, questionnaire, dummy tables and graphs. A statement that the protocol was reviewed and approved by the Research Committee and the Director (and Dean, if applicable) of the institution/hospital. Informed Consent Form compliant to the ICH E6(R2) section 4.8 Case Report Form Proof of Payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits application with complete requirements. The requirements should be included in the MR/NCE application. If application fee is not included in the MR/NCE application payment, pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then, send the proof of payment to FDAC.	1.1 Endorses the application to CDRR for evaluation.	AO 50 s. 2001 Protocol for MR/Post Marketing Surveillance: Php 2,500.00 +1% LRF	*Timeline starts after posting of payment	FDAC Personnel
	1.2 Receives the application from FDAC.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit Personnel
	1.3 Endorses the PMS (Phase IV Clinical Study) application requirements to the Clinical Research Section (CRS) of the PRSDD.	None		Licensing and Registration Division (LRD) Evaluator; and/or CDRR-CRR Unit Personnel
	1.4 Decks/assigns the application to the evaluators of the CRS.	None	1 working day	Clinical Research Section (CRS) Supervisor
If an electronic Notice of Deficiencies (eNOD) was issued by the evaluator, submits complete compliance documents to the evaluator.	2.1 Evaluates the application for completeness and scientific worth.	None	29 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator) or FDRO III /

				Medical Specialist II (Senior Evaluator)
	2.2 Reviews the evaluated application bearing the recommendation of the evaluator. *After checking of the CRS supervisor, any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries, unless client requested for extension).	None	5 working days	CRS Supervisor
	2.3 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief.	None	1 working day	FDRO I/II/III or MS II
	2.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature.	None	1 working day (per batch of applications)	PRSDD Chief
	2.5 Signs and approves the final decision.	None	1 working day (per batch of applications)	CDRR Director
	2.6 Encodes/updates the database and endorses the Approval/Disapproval Letter (final output document) to the AFS Releasing Section. The scanned copy of this document is sent electronically to the client.	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
Receives the documents.	3. Releases the hard copy of the Approval/Disapproval Letter to the client.	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Simultaneously processed with the Monitored-Release Registration application within the 180-day timeline of Monitored-Release application; or processed as post-approval requirement if additional PV activities will be required based on FDA Circular No. 2021-020; Service is covered under RA 3720 and 7394).		Php 2,525.00	At least 40 Working Days	

42. ISSUANCE OF SALES PROMO PERMIT OF PHARMACEUTICAL PRODUCTS (INITIAL AND AMENDMENT)

This permit is issued to concerned parties for the conduct of their sales promotion activities of applicable drug products.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, Traders, and Retailers of Pharmaceutical Products

Fees to be Paid	:	As per DTI-DOH JAO NO. 1 s. 2000: Prescribing a Schedule of Fees and Charges for Sales Promotion Activities Initial: The permit fees for the conduct of sales promotion schemes shall be as follows: Coverage: (Fees) NCR only or in several regions in NCR and Nationwide — Php 1,000 + 1% LRF More than one (1) region in NCR and Nationwide — Php 750 + 1% LRF Several provinces/cities/municipalities within a single region — Php 500 + 1% LRF Single province/city/municipality — Php 250 + 1% LRF The amount of fees for sales promotions (except for discount scheme type of promotion) which includes variables covered by blanket approval (covering a period of one (1) year as prescribed by the Consumer Act) shall be in accordance with the enumerated hereunder or in accordance with geographical areas, whichever is higher: Amount of Prices: (Fees) Up to Php 50,000 — Php 250 + 1% LRF Php 50,000 - Php 150,000 — Php 500 + 1% LRF Php 150,000 - below Php 300,000 — Php 1,000 + 1% LRF Php 300, 001 -Php 500,000 — Php 2,000 + 1% LRF Php 500,001 - Php 1,000,000 — Php 3,000 + 1% LRF Above Php 1,000.000 — Php 5,000 + 1% LRF Amendment: Php 310

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR SALES PROMO PERMIT	
INITIAL	
Accomplished Integrated Application Form	Applicant Company
Letter of Intent for application of Promo Permit	Applicant Company
List of Participating Products in Excel Format (Sheet 3 of Information Sheet)	Applicant Company
Copy of the valid product notification/registration/ exemption	Applicant Company
Information Sheet and Mechanics of the Sales Promotion	Applicant Company
Layout of Promo materials (if applicable)	Applicant Company
Proof of payment	Applicant Company
Self-Assessment Form for Sales Promo Permit	Applicant Company
AMENDMENT	
Accomplished Integrated Application Form	Applicant Company
Letter of Intent specifying the type of amendment	Applicant Company
Copy of previously issued valid promo permit	Applicant Company
Supporting documents for the requested amendment	Applicant Company
Proof of payment	Applicant Company
Self-Assessment Form for Sales Promo Permit	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRR Unit Personnel

4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	11 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)
	4.2 Prints the final response and transmittal, and forwards it to the Senior Evaluator	None	1 working day	
	4.3 Reviews the evaluated application bearing the recommendation of the junior evaluator and forwards the application to the Licensing and Registration (LRD) Chief	None	2 working days	FDRO III (Senior Evaluator)
	4.4 Checks and recommends the decision of the senior evaluator/s by affixing initial/signature		1 working day (per batch of applications)	LRD Chief
	4.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.6 Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
5. Receives the final response (sales promo permit or letter of disapproval)	5. Releases the final response to the client (sales promo permit or letter of disapproval)	None	1 working day	AFS Releasing Section Personnel
	TOTAL:		**20 working days**	

43. PROCESSING OF PRODUCT CLASSIFICATION APPLICATION

The Product Classification is granted to Marketing Authorization Holder in order to identify if the product is classified as a drug, medical device, food supplement or cosmetics or non-registrable in FDA.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All licensed establishments
Fees to be Paid	:	Administrative Order No.-50-2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Product Classification Requirements 1. Letter of intent 2. Complete Technical Profile of the Product, shall include the following: description, formulation/list of ingredients with corresponding amount per unit dose, indication, direction for use, claims (if any), labelling materials/brochures 3. Classification of the product in the country of origin 1. List of countries where the product is currently marketed and the corresponding classification of the product 2. Representative sample 3. Proof of Payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. Pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then send the proof of payment to the FDAC.	2.1 Receives the payment from the applicant for posting Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	*Timeline starts after posting of payment	FDA Cashier/ Landbank FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff
3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	13 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	2 working days	*Clinical Research Section Supervisor*

	3.3 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*PRSDD Chief*
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	3.6 Scans the document with decision and email to the applicant Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
4. Receives the letter	4. Releases the letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL:		PHP 510.00	20 working days	