FACILITATED REGISTRATION PATHWAYS

6. ABRIDGED REVIEW PATHWAY of CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF NEW DRUG PRODUCTS FOR HUMAN AND VETERINARY USE INCLUDING VACCINES AND BIOLOGICALS

This Certificate of Product Registration 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 **Abridged Review Pathway** based on 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 • Initial and MR for human and animal vaccines and biologicals
Fees to be Paid	:	AO 50 s. 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 (for Veterinary, and Vaccines and Biologicals) 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

ELIGIBILITY CRITERIA
(Provided under Sec. IV.B. of Administrative Order No. 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

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 Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information 1. Notarized Integrated Application Form (in excel and pdf formats) (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 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)	 Applicant Company/Manufacturer (For the whole Part I) FDA Website & Cashier

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 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) 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	Applicant Company/Manufacturer (For the whole Part II: Quality)

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 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	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

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 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	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

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: d. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems a. RMP Philippine-Specific Annex (as applicable) b. 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.	

	Applicant Company /Manufacturer Applicant Company /Manufacturer FDA (Applicant Company)

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

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No .47-a, series of 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
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	Applicant Company /Manufacturer

c. GMP certificate of contract 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	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

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, 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)	
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	Applicant Company/ Manufacturer (For whole Part II: Quality)

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	
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 whole Part III: Nonclinical 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 4.1. 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	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

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 1.3. 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 AND INITIAL REGISTRATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No .47-a, series of 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 AO 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
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	Applicant Company

b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	/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 c. Package Insert d. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) which shall include the following: d. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems e. RMP Philippine-Specific Annex (as applicable) f. 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	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. 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 11. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 12. 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 S 6 Container Closure System	Applicant Company/ Manufacturer (For whole Part II: Quality)

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) a. From supplier of API b. From manufacturer of finished product	Applicant Company/ Manufacturer (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/ Manufacturer
11. Stability Studies	Applicant Company/ Manufacturer
12. Labeling Materials (facsimile labels)	Applicant Company/ Manufacturer
13. Representative Sample (upon request of the evaluator)	Applicant Company/ Manufacturer
Additional Requirements:	
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	Applicant Company/ Manufacturer
2. For imported products: a. Certificate of Pharmaceutical Product (CPP) b. Foreign GMP Clearance	Applicant Company/ Manufacturer
3. For new veterinary drugs: a. Pre-clinical studies	Applicant Company/ Manufacturer

b. Protocol for monitored release 4. For fixed-dose combination: Rationale of the Combination 5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	 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 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*
	2. Pre-assesses the completeness of the application and verifies the registration pathway of the application if indeed for abridged 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 *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.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	4. Receives the application from FDAC and encodes/updates the database.	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing
	5. 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	Day 3 1 working day	CDRR *Director* CDRR-CRR

	6. Evaluates the application according to requirements and prescribed standards For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	Day 4-28 25 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/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	None		*FDRO I/II/III*
	*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		
	7. Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 29-38 10 working days	FDRO III

	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 its recommendation on the application particularly on the formulation and labeling	None	Day 39 1 working day	FDRO I/II/III
	9. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 40 1 working day	FDRO IV (Supervisor)
	11. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 41 1 working day	LRD Chief
	12. Signs and approves the final decision	None	Day 42 1 working day	CDRR Director
	13. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 43 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	14. Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 44 1 working day (per batch of applications)	CDRR-Records Personnel
3. Receives the CPR/LOD/Letter	15. Releases the CPR/LOD/Letter to the client	None	Day 45 1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA Circular No. 2022-004).		**TOTAL:**	**45 working days**	