4. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (INITIAL – REPRODUCTIVE HEALTH PRODUCTS)

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
Fees to be Paid	:	AO 50 s. 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). **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

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
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:	
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
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	Applicant Company/Manuf acturer (For whole Part II: Quality)

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 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)	
ADDITIONAL REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED RELEASE REGISTRATION:	
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	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

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 Development76 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 4.1.4.3. 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 Evaluated77 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 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	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

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) 3. 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. For products to be registered using the Collaborative Registration Procedure (CRP), Expression of Interest submitted to WHO 5. 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	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer (FDA) Applicant Company/ Manufacturer

• 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).	

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. 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 (CRR) Unit

	5. Queuing time of the application before decking to evaluators	None	Day 2-21 20 working days	CDRR-CRR Unit Personnel
	6. 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	Day 22 1 working day	LRD Chief
	7. Evaluates the application according to the requirements and prescribed standards	None	Day 22-41 20 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)

If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	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 Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)	None		FDRO I/II/III/ Medical Specialist II/III
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	Day 42-51 10 working days	FDRO III

	9. 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	Day 52 1 working day	FDRO I/II
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 53 1 working day	FDRO III
	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 54 1 working day	FDRO IV (Supervisor)
	12. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 54 1 working day	LRD Chief
	13. The assigned evaluator shall notify the TWG on RH product secretariat for applications which passed the QSE evaluation.	None	Day 55 1 working day	FDRO I/II/TWG RH product secretariat
	14. 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.		Day 56-65 10 working days	TWG RH product secretariat

	15. Issues FDA Advisory on the publication of notice for the submission of petitions, position papers and corresponding evidence of interested parties.	None	Day 66-75 10 working days	CDRR Director/Information and Communication Technology Management Division (ICTMD) Staff
3. Submits petitions, position papers and corresponding evidence from interested parties.	16. 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	Day 76 1 working day	CRR personnel
	17. 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. 19.	None	Day 77 1 working day	FDRO I/II (CRS evaluator)/ Medical Specialist II/III
	18. 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	Day 78-97 20 working days	External consultants

	19. 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	Day 98-106 9 working days	FDRO I/II (CRS evaluator)/ Medical Specialist II/III
	20. 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	Day 107 1 working day	FDA TWG on RH products
	21. 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	Day 108 1 working day	TWG RH product secretariat/ TWG RH Product Chairperson, Vice-Chairperson and Members
	22. Forwards the resolution to the Office of the Director General.	None	Day 109 1 working day	CRR personnel

	23. Signs and approves the resolution. Forwards the signed copy of resolution to CDRR.	None	Day 110 1 working day	Director General
	24. 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	Day 111 1 working day	FDRO I/II/FDRO III
	25. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 112 1 working day	FDRO III
	26. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 113 1 working day	FDRO IV (Supervisor)
	27. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 114 1 working day	LRD Chief
	28. Recommends the final decision by affixing signature.	None	Day 115 1 working day	CDRR Director

	29. Signs and approves the final decision (CPR/LOD).	None	Day 116 1 working day	Director General
	30. Forwards the signed CPR or LOD to the CDRR-CRR	None	Day 117 1 working day	ODG personnel
	31. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	32. 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)	CDRR-Records Personnel
	33. Releases the CPR/LOD/letter to the client	None	Day 120 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**	