OTC-HM-TM-MO

11. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (INITIAL – VETERINARY DRUGS AND PRODUCTS)

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

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 Applicant Company/

3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	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	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)	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:	Applicant Company/ Manufacturer
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	Applicant Company/ Manufacturer
2. For imported products:	Applicant Company/ Manufacturer
a. Certificate of Pharmaceutical Product (CPP)	Applicant Company/ Manufacturer
b. Foreign GMP Clearance	Applicant Company/ Manufacturer
3. For new veterinary drugs:	Applicant Company/ Manufacturer
a. Pre-clinical studies	Applicant Company/ Manufacturer
b. Protocol for monitored release	Applicant Company/ Manufacturer
4. For fixed-dose combination: Rationale of the Combination	
5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR (Applicant Company)
	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.	4. 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*
	5. 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
	6. Queuing time of the application before decking to evaluators	None	Day 2-21 20 working	CDRR-CRR Unit *Personnel*
	7. Decks/Assigns the application to the assigned evaluator	None	Day 22 1 working day	LRD *Chief*
	8. Evaluates the application according to requirements and prescribed standards (Quality)	None	Day 23-71 50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior*
	9. 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	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	Day 72 1 working day	FDRO I/II/III
	10. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 working days	FDRO III
	11. 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 113 1 working day	FDRO I/II/III

	12. 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
	13. 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)
	14. Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	Day 116 1 working day (per batch of applications)	LRD Chief
	15. Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	CDRR Director
	16. 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
	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	Day 119 1 working day (per batch of applications)	CDRR-Records Personnel
4. Receives the CPR/LOD/letter	18. 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, and Republic Act No. 7394 Article 31.		**TOTAL:**	**120working days**	