12. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (INITIAL – OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDY)

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 (based on AO 50 s. 2001) 3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	FDA Website 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)	
a. From supplier of API	Applicant Company /Manufacturer
b. From manufacturer of finished product	
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 (Supplier of API & 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	Applicant Company/ Manufacturer
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).	Applicant Company /Manufacturer
	Applicant Company /Manufacturer
Additional Requirements:	
14. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	
15. For imported products:	Applicant Company /Manufacturer
a. Certificate of Pharmaceutical Product (CPP) or Certificate of Free Sale	Applicant Company/ Manufacturer
b. Foreign GMP Clearance	Applicant Company /Manufacturer
16. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Applicant Company/ Manufacturer
	Applicant Company/ Manufacturer

	Applicant Company/ Manufacturer FDA CDRR (Applicant Company) 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	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
	5. Queuing time of 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	None	Day 22 1 working day	LRD *Chief*
	7. 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	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*
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 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 113 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 114 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 115 1 working day (per batch of applications)	*FDRO IV (Supervisor)*
	12. 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*
	13. Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	*CDRR Director*
	14. 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*
	15. 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	16. Releases the CPR/LOD/letter to the client	None	Day 120 1 working day	*AFS Releasing Section*
(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**	