14. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (INITIAL – HERBAL MEDICINE/TRADITIONALLY-USED HERBAL PRODUCTS)

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/Divisio	**:**	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**	
1. Notarized Integrated Application Form (in excel and in pdf format)	Applicant Company
2. Proof of Payment	Applicant Company
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 Active Raw Material b. From manufacturer of finished product c. Certification of Authenticity of Plant Specimen from the National Museum or any FDA-recognized Taxonomist	Applicant Company (API Supplier & Manufacturer) National Museum or any FDA-recognized Taxonomist
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	NIRPROMP & Applicant Company
11. Stability Studies	
12. Labeling Materials (facsimile)	
13. Evidence of Safety and Efficacy	
14. Representative Sample (upon request of the evaluator	
Additional Requirements: 1. 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.	

1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability 2. For imported products: c. Certificate of Pharmaceutical Product (CPP) d. Foreign GMP Clearance 3. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer 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	
1. Notarized Integrated Application Form (in excel and in pdf format) 2. Proof of Payment 3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable 4. Unit Dose and Batch Formulation 5. Technical Specifications of all Raw Materials 6. Certificate of Analysis of active Raw Material(s) a. From supplier of Active Raw Material b. From manufacturer of finished product c. Certification of Authenticity of Plant Specimen from the National Museum or any FDA - recognized Taxonomist 7. Technical Specifications of Finished Product 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 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 Applicant Company Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company (API Supplier & Finished Product Manufacturer) National Museum or any FDA-recognized Taxonomist Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

12. Labeling Materials (facsimile labels)	Applicant Company/ Manufacturer
13. Evidence of Safety	Applicant Company/ Manufacturer
14. Evidence of Claimed Application	Applicant Company/ Manufacturer
15. Representative Sample	Applicant Company/ Manufacturer
Additional Requirements:	
1. For products in plastic container:	Applicant Company/ Manufacturer
Certificate of Analysis for Test of Migratable Substances/ Leachability	Applicant Company/ Manufacturer
2. For imported products:	Applicant Company/ Manufacturer
a. Certificate of Traditionally –Used Herbal Product	
b. Foreign GMP Clearance	Applicant Company/ Manufacturer
3. Valid LTO (Importer/Manufacturer/Distributor/Trader)	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. 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 of Registration Section and/or Clinical Research Section	None	Day 2-21 20 working days	CDRR-CRR Unit *Personnel*
	6. Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section	None	Day 22 1 working day	*CDRR Director*
	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) / 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	None	Day 72 1 working day	*FDRO I/II/III/ Medical Specialist II*
	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 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	None	Day 115 1 working day	*FDRO IV (Supervisor)*

	12. 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*
	13. Signs and approves the final decision	None	Day 117 1 working day	CDRR Director
	14. Encodes/Updates the Database and Endorses the final output document 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 document 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 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**	