24. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (REGULAR RENEWAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders to continue the manufacture, distribution and sale of pharmaceutical products based on compliance with quality, safety and efficacy standards.

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	:	AO 50 s. 2001 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF Additional (if with variation/s) Payment shall be based on FDA Circular No. 2014-008, Annex D on a per product, per change basis. Surcharge (based on FDA Circular No. 2011-004) Computation: 2 x (renewal registration fee) + 10%* (renewal registration fee) *If the renewal application is submitted on the: First month: 10% First day of the second month: 20% First day of the third month: 30% First day of the fourth month: 40% Any renewal application filed after the 4th month (120th day) shall be treated as an initial application.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Documentary Requirements	
a. Copy of previously issued CPR	Applicant Company
b. Copy of LTO of manufacturer, importer, trader, and/or distributor (and renewal case number with proof of payment)	Applicant Company
c. Copy of Certificate of GMP Clearance for imported product (and/or initial or renewal application, whichever is applicable)	Applicant Company
CHECKLIST OF REQUIREMENTS FOR REGULAR RENEWAL REGISTRATION **FOR PRESCRIPTION PRODUCTS/ OVER-THE-COUNTER PREPARATIONS/ HOUSEHOLD REMEDIES**	
1. Notarized Integrated Application Form (in excel and pdf format)	Applicant Company/FDA
2. Proof of Payment	Website
3. Unit Dose and Batch Formulation	Applicant Company
4. Technical Specifications of Finished Product	Applicant Company/Manufacturer
5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/Manufacture Applicant Company/Manufacturer
6. Assay and Other Test Procedures including Assay with Data Analysis	
7. Stability Studies	Applicant Company/Manufacturer
8. Labeling Materials (actual/commercial label)	
9. Actual commercial samples (w/Certificate of Analysis) (upon request of the evaluator)	Applicant Company/Manufacturer
10. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements:	
1. Post-marketing commitments (if any)	Applicant Company/Manufacturer
2 . For imported products: Foreign GMP Clearance	FDA CDRR
3. For oral solid dosage forms, proof of interchangeability (Bioequivalence study or Biowaiver, whichever is applicable)	Applicant Company/Manufacturer

FOR BIOLOGICALS/SIMILAR BIOTHERAPEUTIC PRODUCTS 1. Integrated Application Form 2. Proof of Payment 3. Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) 4. Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated 5.Labeling Materials (actual/commercial labels) 6.Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) 7.If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	Applicant Company/FDA Website Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: 1. Post-marketing commitments (if any) 2. For products qualifying for Generic Labeling Exemption (GLE): Request for GLE 3. For imported products: Foreign GMP Clearance 4. Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) 5. List of Countries where the vaccine is already licensed and date of approval (for vaccines) 6. Adverse event following immunization report (Summary of Annual Reports) (for vaccines)	 Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
FOR HERBAL MEDICINES/TRADITIONALLY USED HERBAL PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment 3. Unit Dose and Batch Formulation 4. Technical Specifications of Finished Product 5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 6. Stability Studies	 Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer

7. Labeling Materials (actual/commercial label) 8. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) 9. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: 1. Post-marketing commitments (if any) 2. For imported products: Foreign GMP Clearance	 Applicant Company/Manufacturer Applicant Company/Manufacturer
FOR MEDICAL GAS (OXYGEN) 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment 3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable 4. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 5. Certificate of Analysis issued by CIGI for the product 6. Manufacturing Procedure, Production Equipment, Sampling, In-process controls 7. Labeling Materials (actual/commercial label) 8. If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	 Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: 1. Post-marketing commitments (if any) 2. For imported products: Foreign GMP Clearance	 Applicant Company/Manufacturer Applicant Company/Manufacturer
FOR VETERINARY DRUG PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment	 Applicant Company Applicant Company

3.Unit Dose and Batch Formulation	Applicant Company/Manufacturer
4.Technical Specifications of Finished Product	Applicant Company/Manufacturer
5. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/Manufacturer Applicant Company/Manufacturer
6. Assay and Other Test Procedures including Assay with Data Analysis	Applicant Company/Manufacturer
7. Stability Studies	Applicant Company/Manufacturer
8. Labeling Materials (actual/commercial label)	Applicant Company/Manufacturer
9. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator)	Applicant Company/Manufacturer
10. If with previously approved/acknowledged variation applications filed prior to CPR renewal:	
Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	
Additional Requirements: 1. Post-marketing commitments (if any) 2. For imported products: Foreign GMP Clearance	Applicant Company/ Manufacturer FDA CDRR
For Monitored-Release Extension (MRE)	Applicant Company/ Manufacturer
1. Notarized Integrated Application Form (in excel and pdf format)	Applicant Company/ Manufacturer
2. Proof of payment	Applicant Company/ Manufacturer
3. Copy of Latest Certificate of Product Registration (CPR)	
4. Unit Dose and Batch Formulation	Applicant Company/ Manufacturer
5. Actual/Commercial Labeling Materials	Applicant Company/ Manufacturer
Additional Requirements: 1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post-Marketing Surveillance (PMS) Report	Applicant Company/ Manufacturer
2. MRE to Initial: Periodic Safety Update Report (PSUR), or proof of submission	
3. Risk Management Plan (RMP)	Applicant Company/ Manufacturer
4. Periodic Safety Update Report (PSUR)	
5. For imported products: Certificate of Pharmaceutical Product (CPP) Foreign GMP Clearance	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.	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
	5. Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section		Day 2-21 20 working days	CDRR-CRR Unit Personnel
	6. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	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)/
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 (Quality, and/or Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator.		Day 72 1 working day	FDRO I/II/III

	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			
	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/Certificate/Letter/LOD) 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/Certificate/LOD/Letter) to the client, updates the database and website, and endorses the final output	None	Day 119 1 working day (per batch of applications)	AFS-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
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**	