21. ELECTRONIC PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION (e-PCPR) CONVERSION OF PHARMACEUTICAL PRODUCTS

This Certificate of Product Registration is granted to Marketing Authorization Holders for the conversion from Regular CPR [DR-XY] to a Principal Certificate of Product Registration (PCPR) [DRP].

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 with a valid regular CPR
Fees to be Paid	:	A.O 50 s. 2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Principal Certificate of Product Registration (PCPR) Conversion	
1. Copy of current and valid CPR	Applicant
2. Copies of the respective current and valid License to Operate (LTO) of the principal CPR applicant and toll manufacturer (if applicable)	Applicant
3. Proof of payment as per AO 50 s. 2001 (Php 500.00 + 1% LRF)	Cashier

References:	
1. Republic Act 9711 – Food and Drug Administration Act of 2009 2. AO 2005-0031 – Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation. 3. FDA Advisory No.2021-1790 – Guidelines on Principal Certificate of Product Registration Conversion Application using e-Services Portal System. 4. FDA Advisory No. 2022-0417 – Implementation of The Food and Drug Administration (FDA) e-Services Portal System for Principal Certificate of Product Registration (PCPR) Conversion Applications for Drug Products 5. FDA Advisory No. 2022-0907 – Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) "Applications"		None		
2. Select "Certificate of Product Registration" and select "Drug". Select the Product Category, Click on the Principal Certificate of Product Registration (PCPR) Conversion		None		
3. Click "I have read and accepted the terms and conditions stated on this form". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None		

4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None		
5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1. Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None		CDRR Pre-assessor
6. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail		None		
7. Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	2. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for sbank payments;	Php 500.00 + 1% LRF		FDA Cashier

	3. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier
	4. This will prompt automatic decking of application to respective Center	None		ICTMD (eService)
8. Receives acknowledgement receipt through email	5. The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance. *Any minor deficiencies/clarification will be communicated to the clients through electronic communication (e-NOD).	None	Day 1-5 5 working days	CDRR Evaluator

	6. QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	Day 6-8 3 working days	CDRR Supervisor
	7. Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	Day 9-10 2 working days	CDRR Director
9. Receive notification and link of CPR/Letter of Disapproval for printing. Note: Once approved, applicants are required to surrender the original copy of the Certificate of Product Registration (CPR) within 3 working days.		None	0	
	TOTAL:		**10 Working days**	