16. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (ELECTRONIC AUTOMATIC RENEWAL) [e-AR]

This Certificate of Product Registration is granted by the FDA to the Marketing Authorization Holder in order to continue marketing a specific product in the country provided that the conditions for Automatic Renewal stipulated in Book II Article 1 Section 3.B (2) of the IRR of RA 9711 have been fulfilled.

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 Drug Products for Human and Veterinary Use
Fees to be Paid	:	A.O. 50 s. 2001 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Eligibility to Automatic Renewal Registration **Implementing Rules and Regulations (IRR) of Republic Act No. 9711** There shall be automatic renewal of the Certificate of Product Registration (CPR) when the following conditions are satisfied: 1. The application is filed before the expiration date of the registration; 2. The prescribed renewal fee is paid upon filing of the application; and 3. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.	Applicant Company

References: 1. Republic Act 9711 – Food and Drug Administration Act of 2009 2. The Rules and Regulations Implementing Republic Act No. 9711 – The Food and Drug Administration Act of 2009 3. FDA Advisory No. 2021-0999 - Implementation of The Food and Drug Administration (FDA) eServices Portal System for Automatic Renewal (AR) Applications for Drug Products.	

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 classification of the product to be renewed then select "Automatic Renewal Registration for Regular CPR & PCPR" or "Automatic Renewal Registration for CLIDP" whichever is applicable.		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 Reference Number sent through the declared e-mail address		None		

7. Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal).	2. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 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	Day 1 1 working day	FDA Cashier
8. Receives acknowledgement receipt through email	4. 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 QA.	None	Day 2-10 9 working days	CDRR Evaluator

	5. QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	Day 11-15 5 working days	FDRO IV (Supervisor)
	6. 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 16-20 5 working days	CDRR Director
9. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	Applicant
	TOTAL:		**20 Working days**	