RENEWAL & POST-APPROVAL CHANGES (PAC)

15. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF REPRODUCTIVE HEALTH (RH) PRODUCTS (AUTOMATIC RENEWAL) [MANUAL SUBMISSION]

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/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 Reproductive Health Products
Fees to be Paid	:	AO 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 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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secures 14-digit Document Tracking Number (DTN) and schedule of appointment/submission to FDAC.	1. Sends the Document Tracking Log (DTL) bearing the DTN and schedule 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. Decks/Assigns the application to the assigned evaluator	None	Day 3 1 working day	LRD *Chief*/ CRR
	6. Evaluates the application according to requirements and prescribed standards	None	Day 4-11 8 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/*
	7. Prepares draft Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares draft Letter of Disapproval (LOD) when the application does not merit an Approval recommendation	None	Day 11 1 working day	*FDRO I/II*
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 12-14 3 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		*FDRO II*
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*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 15 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 16 1 working day (per batch of applications)	*LRD Chief*
	13. Recommends the final decision by affixing signature when approval of the application is recommended.	None	Day 17 1 working day (per batch of applications)	*CDRR Director*
	14. Signs and approves the final decision	None	Day 18 1 working day (per batch of applications)	FDA *Director General*
	15. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 19 1 working day (per batch of applications)	*CDRR-CRR Unit* *Personnel*

	16. 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 20 1 working day (per batch of applications)	*CDRR-Records Personnel*
4. Receives the CPR/LOD/letter	17. Releases the CPR/LOD/letter to the client	None	Day 20 1 working day	*AFS Releasing Section Personnel*
	TOTAL:	Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF	**20 working days**	