20. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION CONVERSION)

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	:	Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Principal Certificate of Product Registration (PCPR) Conversion	AO 2005-0031 Bureau Circular 11 s. 2006
1. Duly accomplished and notarized Integrated Application Form (in excel and pdf format	Applicant Company/FDA Website
2. Original copy of the CPR	Applicant Company
3. Copies of the respective current and valid License to Operate (LTOs) of the principal CPR applicant and toll manufacturer (if applicable)	Applicant Company
4. Proof of payment as per AO 50 s. 2001 (Php 500.00 + 1% LRF)	Applicant Company

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	c/o FDAC	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	c/o FDAC	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. Decks/ Assigns the application to the assigned evaluator	None	Day 3 1 working day	LRD *Chief*
	6. Evaluates the application according to requirements and prescribed standards	None	Day 4-8 5 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) when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (e-NOD)	None	Day 9-13 5 working days	*FDRO I/II*

	7. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 14 1 working day	*FDRO IV*
	8. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the Section Supervisor (FDRO IV)	None	Day 15 1 working day	*FDRO I/II*
	9. 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	*FDRO IV*
	10. Checks and recommends the decision of the evaluator and supervisor by affixing initial/signature	None	Day 16 1 working day (per batch of applications)	*LRD Chief*
	11. Signs and approves the final decision	None	Day 17 1 working day (per batch of applications)	CDRR *Director*
	12. Encodes/Updates the Database and Endorses the final output document to the CDRR- Records Section	None	Day 18 1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*

	13. Scans, barcodes, and emails the scanned copy to the client; and endorses the final output document to the AFS Releasing Section		Day 19 1 working day (per batch of applications)	CDRR-Records Personnel
4. Receives the CPR/LOD/letter	14. Releases the CPR/LOD/Letter to the client	None	Day 20 1 working day	AFS Releasing Section Personnel
		TOTAL:	**20 working days**	