G. CERTIFICATE OF PHARMACEUTICAL PRODUCTS (COPP), CERTIFICATE OF FREE SALE (CFS), EXPORT CERTIFICATE (EC), AND GENERIC LABELING EXEMPTION (GLE)

These certificates are issued to indicate that the product is registered and marketed in the country; or for export; or exempted from the generic labeling guidelines.

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
Fees to be Paid	:	COPP: Php 500.00 each/per product/per country + 1% LRF CFS: Php 500.00 each/per product/per country + 1% LRF EC: Php 500.00 each/per product/per country + 1% LRF GLE: Php 500.00 each/per product/per year for low volume of importation + 1% LRF Php 500.00/product for special handling + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Certificate of Pharmaceutical Product	
1. Application Form	Applicant Company
2. Valid Certificate of Product Registration	Applicant Company
3. Valid License to Operate (LTO) of manufacturer/exporter	Applicant Company
4. Valid cGMP of manufacturer	Applicant Company
5. Immediate and secondary labeling materials	Applicant Company
6. Unit Dose Formulation	Applicant Company
7. Payment of P 500.00 each/per product/per country	Applicant Company

Certificate of Free Sale	
1. Application Form	Applicant Company
2. Valid Certificate of Product Registration	Applicant Company
3. Valid License to Operate (LTO) of Manufacturer/exporter	Applicant Company
4. Payment of P 500.00 each/per product/per country	Applicant Company
Export Certificate	Applicant Company
1. Application Form	Applicant Company
2. Valid Certificate of Product Registration	Applicant Company
3. Valid License to Operate (LTO)	
4. Quantity, batch number, manufacturing and expiry dates of the drug product/s to be exported	Applicant Company
5. Payment of P 500.00 each/per product/per country	Applicant Company
Generic Labeling Exemption	Applicant Company
1. Completely filled and signed Integrated Application Form (in excel and pdf format)	Applicant Company
2. Signed Letter of Request (stating the basis of exemption)	Applicant Company
3. Copy of valid CPR with attachments, if applicable	Applicant Company
4. License to Operate as Drug Importer (for low volume of importation)	Applicant Company
5. Facsimile of the labeling materials (primary and secondary packaging materials)	Applicant Company
6. Copy of previously approved certificate of generic labeling exemption (for renewal applications)	Applicant Company
7. Market forecast for the period applying for, in case of low volume of importation (must be specified monthly and separated with the letter of request)	Applicant Company
8. Proof of Payment	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		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	3. 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.	4. 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*
	5. 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

	6. Decks/Assigns the application to the assigned evaluator	None	Day 2 1 working day	LRD Chief/ CRR Unit *Personnel*
	7. Evaluates the application according to requirements and prescribed standards	None	Day 3-12 10 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior*
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 Certification issuance 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	None	Day 11-13 3 working days	*FDRO I/II*
	8. Prepares the final output document (Certification /LOD), affixes initial, and forwards it to the Section Supervisor	None	Day 14 1 working day	*FDRO I/II*
	9. Reviews the final output document, signs and forwards it to the Licensing and Registration (LRD) Chief	None	Day 15 1 working day	*FDRO IV* *(Supervisor)*
	10. Checks and recommends the decision of the evaluators and supervisor by affixing 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 AFS Releasing Section	None	Day 18-19 2 working days (per batch of applications)	*CDRR-CRR Unit Personnel*
4. Receives the Certification /LOD	13. Releases the Certification /LOD to the client	None	Day 20 1 working day	*AFS Releasing Section Personnel*
		TOTAL:	**20 working days**	