C. FOREIGN GOOD MANUFACTURING PRACTICE (GMP) CLEARANCE (DESKTOP EVALUATION) [FOR PIC/S-MEMBER COUNTRIES]

This Clearance is issued to Drug Importers to assure GMP compliance of their Foreign Drug Manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP Inspection, as appropriate. This is a requirement for product registration.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Importers of Pharmaceutical Products
Fees to be Paid	:	FDA Circular No. 2014-016 Initial Application of GMP Clearance Php 5,000.00 (per importer per manufacturer per site) + 1% LRF + Php 5,000.00 (FGC Unit review) + 1% LRF Renewal: Php 2,000.00 + 1% LRF Re-issuance of GMP Clearance: Php 1,000.00 + 1% LRF If recommended for Foreign Drug Manufacturer GMP Inspection Application Fee for inspection: Php 3,000.00 + 1% LRF (per application per importer per site) Inspector's Fees ASEAN: US$ 3,500.00 + UNDP-DSA* Asia Pacific: US$ 7,000.00 + UNDP-DSA* Others: US$ 10,500.00 + UNDP-DSA* Accommodations, travel, translator (if necessary), and other incurred fees: Shall be accomplished by importer(s) * UNDP-DSA is per inspector; the fixed fee is per inspection

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
GENERAL REQUIREMENTS DURING FILING AND RECEIVING OF APPLICATIONS AT THE FOOD AND DRUG ACTION CENTER (FDAC) [as per FDA Circular No. 2014-003]: 1. Complete application documentary requirements in a preferred document format stored in USB device (see complete list of requirements below). 2. Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier - One copy of the OnColl payment slip will be collected by the Central Receiving for endorsement to Accounting.	FDA Website/ Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks
CHECKLIST OF REQUIREMENTS FOR FGMP CLEARANCE APPLICATIONS 1. Foreign GMP Evidence Evaluation • Letter of Request • Annex B • Annex E • GMP Evidence 2. Foreign GMP Inspection • Letter of Request • Annex C • Notice of Foreign Inspection • Annex D 3. Renewal of GMP Clearance • Letter of Request • Annex B • Annex E • GMP Evidence • Copy of GMP Clearance previously issued •	Applicant Company Applicant Company Applicant Company

4. Proof of payment (based on FDA Circular No. 2014-016)	FDA Cashier/Other FDA-Authorized Payment Portals or

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph on the assigned submission date as per FDA Circular No. 2020-026, Annex A.	1. Pre-assesses the completeness of the application.			FDAC *Personnel*
	2. Releases the result of the pre-assessment 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*

2. 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 2 1working day	CDRR Director/ CRR Unit *Personnel*
	6. Evaluates the application according to requirements and prescribed standards	None	Day 3-52 50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	7. When the approval of the application is recommended, prepares certification approval. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). When the application is recommended for foreign inspection, prepare a Notice of Inspection. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	Day 53 1 working day	*FDRO I/II/III*
	8. Encodes and prints the appropriate document for issuance	None	Day 54 1 working day	*FDRO I/II/III*
	9. Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 55 1 working day	*FDRO III*
	10. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 56 1 working day (per batch of applications)	*LRD Chief*
	11. Signs and approves the final decision	None	Day 57 1 working day (per batch of applications)	*CDRR Director*

	12. Encodes/Updates the Database and Endorses the final output document to the CDRR-Records	None	Day 58 1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	13. Scans and Endorses the Certification / Extension of Validity and updates the database and website	None	Day 59 1 working day (per batch of applications)	*CDRR-Records Personnel*
3. Receives the Certification / Notice of Inspection/LOD/ Extension of Validity	14. Releases the Certification/ Notice of Inspection/LOD/ Extension of Validity to the client	None	Day 60 1 working day	*AFS - Releasing Section Personnel*
Service is covered Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 60 working days was proposed.		**TOTAL:**	**60 working days**	