B. FOREIGN GOOD MANUFACTURING PRACTICE (GMP) CLEARANCE (DESKTOP EVALUATION) [FOR NON-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 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 • Annex C (for Non-PIC/S countries) 2. Foreign GMP Inspection • Letter of Request	Applicant Company Applicant Company

• 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 • Annex C (for Non-PIC/S countries) 4. Proof of payment (based on FDA Circular No. 2014-016)	Applicant Company 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
.	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. 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*	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 ICTMD (for Certification/ Extension of Validity)/ or Releasing Section (for Notice of Inspection/LOD) *Aside from the hard copy, Notice for Inspection will also be e-mailed to the client	None	Day 58 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	13. Scans the Releases the Certification/ Extension of validity and updates the database and website	None	Day 59 1 working day (per batch of applications)	AFS-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 *This excludes the application for Foreign GMP Inspection and the inspection proper. The applicant is given 90 working days upon receipt of Notice for Inspection to apply for Foreign GMP Inspection	None	Day 60 1 working day	FDAC Releasing Section Personnel

4. Endorse Recommendation with complete documents and requirements *Recommendation after on-site inspection	15. Accepts the endorsement with complete documents and requirements and encodes/updates the database	None	Day 61 1 working day	Field Regulatory Operations Office and Center for Drug Regulation and Research (CDRR) – Central
	16. Decks/Assigns the application to the assigned evaluator	None	Day 62 1 working day	CDRR Director/ CRR Unit
	17. Evaluates the application according to requirements and prescribed standards	None	Day 63-112 50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior
	18. When the approval of the application is recommended, prepares certification. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). *Any clarifications will be communicated to Drug GMP Inspectorate Task Force	None	Day 113 1 working day	FDRO I/II/III
	19. Encodes and prints the appropriate document for issuance	None	Day 114 1 working day	FDRO I/II/III

	20. Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day	FDRO III
	21. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 116 1 working day (per batch of applications)	LRD Chief
	22. Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	CDRR Director
.	23. Encodes/Updates the Database and Endorses the final output document to the CDRR-Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	24. Scans and Endorses the Certification/LOD to AFS-Releasing Section	None	Day 119 1 working day (per batch of applications)	CDRR-Records Personnel
5. Receives the Certification/LOD	25. Releases the Certification/LOD	None	Day 120 1 working day	AFS Releasing Section Personnel
Service is covered under Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 120 working days was proposed.		**TOTAL:**	**120 working days**	