E. CLEARANCE AND CERTIFICATE FOR FOREIGN DONATIONS

This certificate and clearance are issued for foreign drug donations in support of the service and programs of the health sector.

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
Fees to be Paid	:	Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order No. 2016-0004: Revised Guidelines in the Facilitation and Management of Foreign Donations involving Health and Health-Related Products	
I. Criteria for Acceptable Foreign Drug Donations 1. Listed in the Latest Edition of the Philippine National Formulary 2. For pharmaceuticals which are not included in the Latest Edition of the Philippine National Formulary (PNF), must satisfy at least one of the following conditions: • Must contain the same active ingredients, dosage form and strength as those products already approved by and registered at FDA Philippines; or • Orphan drugs and drugs for compassionate use; or • Critically needed drugs (Note: Subject to approval by the Secretary of Health) 3. Must NOT be classified under the following: • Experimental/investigational drugs and MR registration of FDA Philippines • Regulated, prohibited and/or dangerous drugs of PDEA 4. Must have a shelf-life of at least 12 months (or 1 year) at the expected date of arrival 5. For pharmaceuticals with shelf life below 12 months, must satisfy at least one of the following conditions:	Applicant Company Applicant Company

● The product has a total shelf-life of less than 2 years AND has a remaining of at least one-third (1/3) of its shelf-life. ● Recommended as suitable for distribution as per case assessment by the DOH/TWG and approved by the Secretary of Health despite the limited product shelf-life remaining	
II. Requirements	
II-A. Administrative Data	
1. Endorsement Letter from the Bureau of International Health Cooperation (BIHC) – DOH	BIHC – DOH
2. Letter of intent to donate	Applicant Company
3. Authenticated Deed of Donation (Philippine Embassy/Philippine Consulate)	Philippine Embassy/Philippine
4. Letter of Concurrence or Acceptance	Consulate Applicant Company
5. List of all drug products to be donated with the following information:	Applicant Company
● International Nonproprietary Name (INN) or Generic name	
● Brand name (if any)	
● Dosage Form and Strength	Applicant Company
● Batch/Lot Number	Applicant Company
● Expiration Date	
● Total quantity of batch/lot of products to be donated	
6. Distribution plan/ Allocation list of intended beneficiaries	Applicant Company
7. Photocopy of shipping documents such as bill of lading airway bill, commercial invoice, and packing list	Applicant Company
8. Copy of Post donation report (where applicable)	
9. Proof of payment (PHP 510.00)]	Applicant Company
II-B. Quality	Applicant Company
1. Certificate of Pharmaceutical Product (CPP)	Applicant Company
2. For countries not issuing CPP, the following shall be submitted:	
● Current Good Manufacturing Practice (CGMP) Certificate issued by the drug regulatory authority of the product's country of origin	Applicant Company
● Certificate of Free Sale (CFS) authenticated by the territorial Philippine Consulate	Applicant Company
3. Certificate of Analysis (CoA) per batch/lot of products	Applicant Company
4. Complete labelling materials, i.e., primary and secondary packaging, and package insert, which must contain texts in English/English translation of ALL of the following mandatory	Applicant Company

information: ● International Nonproprietary Name (INN) or Generic name ● Brand name (if any) ● Dosage Form and Strength ● Mode of Administration ● Batch/Lot Number ● Expiration Date ● Formulation ● Storage conditions	

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.letters.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 1 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 1 1 working day	*LRD Chief/ CRR Unit Personnel*
	6. Evaluates the application according to requirements and prescribed standards	None	Day 1 1 working day	*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 Clearance Letter/Certificate of Foreign Donated Product Registration 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 2-13 1-11 working days (dependent on the amount of the received requests and the total number of batches/lots of products to be donated)	*FDRO I/II*
	7. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 14 1 working day	*FDRO III*
	8. Prepares the final output document (Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	Day 15-17 1-3 working days (dependent on the amount of the received requests and the total number of batches/lots of products to be donated)	*FDRO II*
	9. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 18 1 working day	*FDRO III*

	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None		*FDRO IV (Supervisor)*
	11. Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	Day 19 1 working day (per batch of applications)	*LRD Chief*
	12. Signs and approves the final decision	None	Day 19 1 working day (per batch of applications)	*CDRR Director*
	13. Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	Day 20 1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
4. Receives the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval	14. Releases the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval to the client	None	Day 20 1 working day	*AFS Releasing Section Personnel*
	TOTAL:	**PHP510.00**	**20 working days**	