PRSDD

H. BUREAU OF CUSTOMS (BOC) CLEARANCE [IMPORT PERMIT AND EXPORT PERMIT)

The BOC Clearance is granted to Marketing Authorization Holder to allow importation or exportation of drug products used as samples for registration and as test samples or reference products for Bioavailability/Bioequivalence studies.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
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/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Import Permit a. Samples for registration and reference product for the conduct of BA/BE Studies b. Product Developmental Studies c. Comparative Dissolution Profile d. Biowaiver	Applicant Company
1. Letter of Application It should include the following: ·name of requesting party [personal/ Position]; ·itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength and ·an estimated quantity/ volume needed ·Country of Origin ·Purpose of the request ·A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution. 2. Proof of payment (Php 500 + LRF) per product 3. Proforma invoice (includes batch number & expiry date) 4. Certificate of Analysis 5. Copy of License to Operate	 Applicant Company Applicant Company Applicant Company Applicant Company

Export Permit a. Samples for registration and reference product for the conduct of BA/BE Studies b. Product Developmental Studies c. Comparative Dissolution Profile d. Biowaiver e. Return of Complaint Samples	
1. Letter of Application It should include the following: ·name of requesting party [personal/ Position]; ·itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength and ·an estimated quantity/ volume needed ·Purpose of the request ·A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution. 2. Proof of payment (Php 500 + LRF) per product 3. Proforma invoice (includes batch number & expiry date) 4. Certificate of Analysis 5. Actual photo of the drug product to be exported 6. Proof of Purchase (i.e. Official Receipt) from a reputable local source of the product.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for pre-assessment through clinicalresearch@fda.gov.ph	1. 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.	None		FDAC *Personnel*

	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).			
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 1 working day	CDRR Director/ CRR Unit *Personnel*

	6. Evaluates the application according to requirements and prescribed standards	None	Day 2-4 3 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	7. Reviews the evaluated application bearing the recommendation of the Evaluator	None	Day 5 1 working day	Clinical Research Section *Supervisor*
	8. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 5 1 working day	*FDRO I/II/III*
	9. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 6 1 working day (per batch of applications)	*PRSDD Chief*
	10. Signs and approves the final decision	None	Day 7 1 working day (per batch of applications)	*CDRR Director*
	11. Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	Day 7 1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*

3. Receives the permit or final response	12. Releases the permit or final response to the client	None	Day 7 1 working day	AFS Releasing Section *Personnel*
	TOTAL:	**PHP510.00**	**7 Working Days**	