R. IMPORT LICENSE NOTIFICATION

The IL Notification is submitted by the Sponsor, Clinical Research Organization and/or Principal Investigator quarterly of every shipment of investigational drug products and ancillary supplies entering the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All licensed establishments
Fees to be Paid	:	AO 50 s. 2001, FDA Circular 2012-007-A Php 500.00 + 1% LRF per shipment

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Import License Notification Requirements	
1. Cover Letter (FDA-CRS Form 2.0)	Applicant Company
2. Proof of Payment	Applicant Company
3. Investigational Product Importation Report (FDA-CRS Form 9.0)	Applicant Company
4. Ancillary Supplies Importation Report (Appendix D4), if applicable	Applicant Company
5. Copy of Proforma Invoice/s	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.letters.cdrr@fda.gov.ph For COVID-19 related applications, sends through clinicalresearch@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		FDAC *Personnel*
3. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl 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 3 1 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	7. Encodes/Updates the Import License Database	None	Day 3 1 working days	*FDRO I/II/III Evaluator)*
	TOTAL:	**PHP 510.00/ shipment**	**3 working days**	