Q. IMPORT LICENSE AMENDMENT

The IL Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the initial IL issued in terms of its validity and request of additional quantity of investigational drug products and ancillary supplies needed for the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsor, Contract Research Organizations, Importer, and Principal Investigator
Fees to be Paid	:	AO 50 s. 2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Import License Amendment (Extension of Validity and Addition of Quantity/Item) 1.Cover Letter (FDA-CRS Form 2.0) 2. Investigational Product Information (FDA-CRS Form 4.0) 3. Import License Application Form (FDA-CRS Form 5.0) 4. Rationale for the request and/or supporting data 5. Proof of payment	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	3. 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.	4. 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*
	5. 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 Personnel
	6. Decks/Assigns the application to the assigned evaluator	None	Day 2 1 working day	CDRR Director/ CRR Unit

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	7. Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	Day 3-15 13 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	8. Reviews the evaluated application bearing the recommendation of the evaluator	None	Day 16-17 2 working days	Clinical Research Section Supervisor
	9. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 17 1 working day	FDRO I/II/III
	10. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 18 1 working day (per batch of	PRSDD Chief
	11. Signs and approves the final decision	None	Day 19 1 working day (per batch of applications)	CDRR Director
	12. Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	Day 20 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

4. Receives the letter	13. Releases the letter to the client	None	Day 20 1 working day	FDAC Releasing Section
	TOTAL:	**PHP 510.00**	**20 working days**	