13. RENEWAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	**Php5,000.00 + 1% LRF for renewal with 5 years validity** **Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)** **Late Renewal Fees (as per FDA Circular 2011-004)**

Timeline (after expiry date of certificate)	Validity of certificate (in years)	Fee	Laboratory Fee (c/o NRL)	Surcharge	Penalty	LRF	Total
a. First month (10% penalty)	5	5,000.00		10,000.00	500.00	50.00	15550.00
b. 1st day of the second month (20% penalty)	5	5,000.00		10,000.00	1,000.00	50.00	16050.00
c. 1st day of the third month (30% penalty)	5	5,000.00		10,000.00	1,500.00	50.00	16550.00
d. 1st day of the fourth month (40% penalty	5	5,000.00		10,000.00	2,000.00	50.00	17050.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number.	Applicant
2. Notarized Application Form • Shall be completely filled-up; • Model / Reference Number / Sizes / Codes shall be properly identified; • Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa • For kits/sets, identify the complete contents/inclusions on the space provided for device name; • For multiple CPR schemes, an annex page may be attached. However, the product name and model / reference number / size/ code must be specified to which CPR it belongs to; • For multiple models / reference number / size / codes, an annex page may be attached; • The Product Registration Number must be indicated (RR/IVDR); • Shall be signed by the proper authority as indicated on the form; • Re-using forms is not acceptable since this is a legal document.	Applicant Form may be downloaded on the FDA website
3. License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. • Shall be valid • The principal shall be reflected on the list of sources.	Applicant
4. Copy of the front and back pages of the latest Certificate of Product Registration	Applicant

5. Foreign Agency Agreement / Letter of Authorization. • Shall be valid. • Shall be authenticated/apostilled by the territorial Philippine Consulate. • The product being applied must be indicated. • For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. • For open-dated agreements/authorizations, if the certificate is beyond the 5- year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. • For locally manufactured medical devices with exclusive distributor, the agreement should be duly notarized. • For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	Applicant or Principal/Source/ Manufacturer
6. Government issued a certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. • Shall be valid • Shall be authenticated/apostilled by the territorial Philippine Consulate • For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. • The product being applied must be indicated in the scope. • For locally manufactured products, valid LTO of the manufacturer.	Principal/Source/ Manufacturer
7. Real time stability test data and results which shall include: • shelf life study • in-use stability study Note : Shall be performed on at least three (3) different product lots.	Principal/Source/ Manufacturer

8. Clear and readable photos of actual labeling materials ● Immediate label ● secondary packaging ● box label ● package insert/brochure. ○ shall include blood sample collection and handling ○ performance study results and summary ○ cross reactivity and list of potential interfering substances (if applicable) ○ warnings and precautions ○ information of the manufacturer ○ revision number	Applicant
9. For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. No. of samples required will depend on the requirement of each NRL.	Applicant
10. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
● All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. ● Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) ● The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. ● Schedule of submission will be generated by the FDA and sent through email to the client. ● Endorsement to the NRL depends on the schedule performance re-evaluation which will be indicated at the back of the certificate.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting.	PHP5,050.00	**Timeline starts after posting of payment**	FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3 . FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	4. CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	5. The technical evaluator reviews the application. Recommends approval or disapproval. Includes endorsement to NRL if the product is scheduled for performance re-evaluation.	None	5 working days**	Technical Evaluator

	Performance Testing	**c/o NRL**	**Timeline depends on the NRL procedure**	**c/o the National Reference Laboratory**
	6. Review of Performance Evaluation report	None	2 working days	Technical Evaluator
	7. Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	8. Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
	9. Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	10. Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	11. Scanning and barcoding of CPR.	None	1 working day	AFS Records Officer / Administrative Officer
	12. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
	TOTAL	**PHP5,050.00**	**20 working days*** **	

**Day 1 commences upon the receipt of the proof of payment / posting of payment.*
***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.*
****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*