23. APPLICATION FOR VARIATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF IN-VITRO DIAGNOSTIC DEVICES/REAGENTS AND CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) OF MEDICAL DEVICES

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	:	Php500.00 + Php10.00 = Php510.00 Other fees: Extension of shelf life: Php1,000.00 + Php10.00 = Php1,010.00 Change in brand name: Php2,500.00 + Php25.00 = Php2,525.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name and Address of Manufacturer/Trader/Importer/ Distributor	
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking Number	Applicant
2.Valid License to Operate (LTO) reflecting the new business name and address of manufacturer/trader/importer/distributor with the source reflected in the LTO	Applicant
3. Original Certificate of Product Registration (CPR) - Should submit back and front sides	Applicant
4. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant
Change in Ownership (Inclusion/Deletion or Change in Trader/Importer/Distributor)	

1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Valid LTO reflecting the source	Applicant
3. Termination of Contract/Deed of Assignment	Applicant or Principal/ Source/ Manufacturer
4. Agreement with the new company - must be valid	Applicant or Principal/ Source/ Manufacturer
5. Original CPR - Should submit back and front sides	Applicant
6. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant

Request for Change of Shelf Life	**Where to secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Previously submitted stability data	Principal/ Source/ Manufacturer
3. Real time data supporting the change of shelf life - Must be signed by the person who performed the analysis	Principal/ Source/ Manufacturer

4. Copy of CPR - Should submit back and front sides	Applicant
5. Complete labeling requirements - Submit current and proposed labels	Applicant or Principal/ Source/ Manufacturer
Change of Manufacturing Site (Same Subsidiary) With No Change in The Formulation, Equipment, and Manufacturing Procedure	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. . Submit justification or supporting documents to show that the proposed manufacturer is a subsidiary of the current or approved manufacturer	
3. Letter from the manufacturer stating that there is no change in the formulation, equipment and manufacturing procedure	Principal/ Source/ Manufacturer
4. Valid LTO	Applicant
5. Copy of submitted Notification of Source - The list of sources should reflect the proposed manufacturing site	Applicant
6. Formulation (for solutions) or List of Raw Materials (with the corresponding amount of raw materials used, if applicable) issued by the current and proposed manufacturer	Principal/ Source/ Manufacturer
7. Manufacturing flowchart (current and proposed) Include brief narrative description of the manufacturing flowchart	Principal/ Source/ Manufacturer
8. Finished product specification (current and proposed)	Principal/ Source/ Manufacturer

9. For Imported Products – authenticated or apostilled GMP/ISO Certificate reflecting the new manufacturing site The GMP/ISO certificate should be valid	Principal/ Source/ Manufacturer
10. Sterilization process and latest result of sterilization validation conducted/issued by the new manufacturing site	Principal/ Source/ Manufacturer
11. Valid ISO Certificate of the sterilizing company (if there is a change in sterilization company)	Principal/ Source/ Manufacturer
12. Copy of CPR - Should include back and front sides	Applicant
13. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/ Source/ Manufacturer
Change of Brand Name (From Generic to Brand, Change of Brand to Another, Deletion of Brand)	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Should include back and front sides	Applicant
3. Certificate from IPO for local brand name. For imported products, the manufacturer's declaration that allows the use of the brand name.	Applicant
4. Official letter from the product owner regarding the change of brand name and declaration that there is no other change to the product/label except for the brand name	Principal/ Source/ Manufacturer

5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/ Source/ Manufacturer

Change of Storage Condition	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

Change/Additional Indications	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Approval letter issued by a government agency or notified body	Principal/Source/ Manufacturer
4. Studies to support the additional indication	Principal/Source/ Manufacturer
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Re-Packer/Packer	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Termination of contract with the previous re-packer/packer	Applicant or Principal/Source/ Manufacturer
3. Agreement of with the new re-packer/packer	Applicant or Principal/Source/ Manufacturer
4. Copy of CPR - Submit front and back sides	Applicant
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Label Design	Where to Secure
1. Letter of request - Should indicate the reason for change - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved label design	Applicant
4. Proposed label with the new design	Applicant or Principal/Source/ Manufacturer
Change of Packaging	**Where to Secure**

1. Letter of request - Should indicate the reason for change - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Appropriate scientific data on new packaging	Principal/Source/ Manufacturer
4. Proof that no interaction between the product and packaging material occur	Principal/Source/ Manufacturer
5. Comparative tabulated format of specifications of currently approved and proposed packaging material	Applicant or Principal/Source/ Manufacturer
Additional Presentation **[e.g. (1) Registered box x 100's, additional presentation of 1 box x 500's; (2) registered 60mL, additional of 120mL]**	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved and proposed presentation	Applicant
Re-classification (from other classification to Medical Device)	**Where to Secure**
1. Letter of request	Applicant
2. Letter from the other Center regarding re-classification of the product (if applicable)	Applicant
3. Original CPR issued by another Center	Applicant
4. Complete requirements for initial registration	Applicant

Addition of Codes/Reference Number/Article Number	Where to Secure
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Declaration from the manufacturer that there is no change in the manufacturing process, sterilization process and raw materials	Principal/Source/ Manufacturer
4. Provide previous list of raw materials and manufacturing flowchart of the previously approved codes	Principal/Source/ Manufacturer
5. List of raw materials and manufacturing flowchart for the proposed code/s	Principal/Source/ Manufacturer
6. Complete tabulated format of the finished product specification of the currently approved codes and proposed codes	Principal/Source/ Manufacturer
7. Colored photos of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
8. Labels of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
Deletion of Codes/Reference Number/Article Number	**Where to Secure**
1. Letter of request - Indicate the reason for deletion - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Official letter from the product owner regarding the deletion	Principal/Source/ Manufacturer
3. Copy of CPR - Submit front and back sides	Applicant

Additional Sterilization Site	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Sterilization procedure and revalidation protocol issued by the currently approved sterilizing company.	Principal/Source/ Manufacturer
4. Sterilization procedure and revalidation protocol issued by the proposed sterilizing company.	Principal/Source/ Manufacturer
5. Latest result of sterilization revalidation of the new sterilizing company	Principal/Source/ Manufacturer
6. ISO Certificate of the new sterilizing company	Principal/Source/ Manufacturer

Change in Instructions for Use	**Where to Secure**
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant

3. Previously approved instructions for use	Applicant or Principal/Source/ Manufacturer
4. Proposed instructions for use	Principal/Source/ Manufacturer
5. For technical changes, submit study to support the change in instructions for use	Principal/Source/ Manufacturer

Change/Addition of Source of Raw Materials	**Where to Secure**
1. Letter of request - Indicate the reason for the change/addition of source of raw materials - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Comparative tabulated format of the analysis of raw materials of the currently approved and new source	Applicant or Principal/Source/ Manufacturer
4. Comparative tabulated format of finished product specification of the currently approved and new source	Applicant or Principal/Source/ Manufacturer

Change of Test Procedure	**Where to Secure**
1. Letter of request - Indicate the reason for the change of test procedure - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Copy of CPR - Submit front and back sides	Applicant
3. Description of the analytical methodology, a summary of validation data and comparative analytical results between the currently approved and proposed test	Principal/Source/ Manufacturer
Submission schedule is as follows: > For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. > For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

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 and pays the corresponding fee.	1. Receiving officer generates a Document Tracking Number (DTN) and send and acknowledgment email / order of payment to the client.			FDAC Officer
2. The applicant company receives the Order of Payment and pays the fee through the FDAC Cashier or through the other means prescribed by the FDA. The Order of Payment is only valid for 24 hours after issuance.	2. FDA receives the payment from the applicant company.	*Fees depend on the total amendment request of the client.	**Timeline starts after posting of payment**	FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to the FDAC through email.	3. FDAC forwards the application to the CDRRHR.		1 working day	FDAC Officer

	4. Decking of the application to the evaluator.			CDRRHR Administrative Staff
	5. The technical evaluator reviews the application and recommends approval/disapproval.		11 working days**	Technical Evaluator
	6. Quality Assurance – checking and recommendation of the Supervisor.		3 working days	LRD Chief
	7. Preparation of Letter of Approval or Disapproval of Variation		1 working day	Technical Evaluator
	8. Final approval and disapproval and signature of the Center Director.		1 working day	LRD Chief
	9. Scanning of the approval letter.		1 working day	LRD Chief
	10. Transmitting of the approval letter to the Records Section.		1 working day	Technical Evaluator
	11. Queuing and endorsement to the FDA Releasing Section		1 working day	Administrative Officer
	TOTAL	**Php510.00/ Php1,010.00/ Php2,525.00**	**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.*