10. APPLICATION FOR CERTIFICATE OF FREE SALES (CFS)

Center/Office/Division	**:**	CDRRHR-LRD
Classification	**:**	Complex
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 LRF per product**

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. 1 Letter of Intent regarding application for Certificate of Free Sale • List of all devices must be enumerated in one letter only. • If the application is more than one CMDR/CMDN or if the product contains codes. The client must submit a Word Copy of the Letter of Intent.	Applicant
2. 1 copy of Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN). • The CPR must be valid. • For CMDR's/CMDN's currently undergoing the Amendment/Variation process, a letter of approval must be secured by the company prior to CFS application.	Applicant
3. License to Operate as Medical Device Manufacturer/ Exporter. • Must be valid • For cases that the company is not the Manufacturer or Trader, they must apply for additional activity as an Exporter • For LTO currently undergoing the renewal process, submit proof of application for LTO renewal, including Official Receipt.	Applicant
4. Fee • Computation of fee is per CPR as indicated in the letter of intent.	Applicant
5. If the Manufacturer/Trader is different from the Exporter, submit a copy of the agreement/authorization allowing them to export the medical device.	Applicant or 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.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	**Timeline starts after posting of payment**	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	PHP510.00		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		FDAC Officer
	4. CDRRHR assigns the application to evaluator	None	1 Working day	CDRRHR Admin Staff

	5. The technical evaluator reviews the application. Recommends approval or disapproval.	None	7 working days	Technical Evaluator
	6. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	7. Assigning of numbers and Printing of certificates.	None	2 working days	Technical Evaluator
	8. Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	9. Scanning and transmitting of certificates to the Record Section.	None	2 working days	CDRRHR Administrative Staff
4. Pick-up of Certificate	10. Queuing and endorsement to FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	**PHP510.00**	**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.*