



11. APPLICATION FOR COMPASSIONATE PERMIT

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, Patient/End-User of Medical Device
Fees to be Paid	: Php500.00 + Php10.00 LRF per permit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. 1 Letter of intent which will include a brief description of the patient, attending physician, list of specialists who will perform the administration of the medical device, the quantity of the medical device required to perform the treatment and the proposed schedule of the medical attention.	Applicant
2. Attending physician's profile.	Applicant
3. License to Operate as Medical Device Importer/Distributor if the product is to be supplied by a company.	Applicant
4. Letter of information regarding the importer if the medical device is to be imported by a private individual.	Applicant
5. Certificate of Product Registration from the country of origin of the medical device to be used. If the medical device is locally manufactured, copy of the License to Operate as Medical Device Manufacturer.	Principal/Source/Manufacturer
6. Technical description of the medical device from the manufacturer; not downloaded from the company's website.	Principal/Source/Manufacturer
7. Justification letter from the attending physician regarding the urgency of the use of the medical device.	Applicant
8. Medical abstract of the patient.	Applicant
9. A waiver of FDA responsibility from any damage or injury arising from the use of the unregistered medical device to be signed by the applicant company, a relative of the patient and the attending physician.	Applicant
10. A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device in the patient.	Applicant



<p>Submission schedule is as follows:</p> <ul style="list-style-type: none"> 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 	
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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	FDA 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. Data Controller assigns the application to evaluator.	None	1 working day	Data Controller



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