28. COMPLIANCE FOR VARIATION APPLICATIONS

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	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	Applicant
2. Copy of the Notice of Deficiencies	Applicant
3. Compliance Documents	Applicant / Principal/Manufacturer
NOTES: • 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. Submission 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 compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiencies. *	1. Receiving officer sends an acknowledgment email to the client.	None	1 working day	FDAC Officer
	2. FDAC forwards the compliance file to CDRRHR.	None	1 working day	FDAC Officer
	3. CDRRHR receives the compliance file and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	4. Technical evaluation of application. Recommendation for approval or disapproval.	None	10 working days	Technical Evaluator
	5. Quality Assurance - Checking of recommendation of the Supervisor.	None	3 working days	LRD Chief
	6. Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	7. Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	8. Queuing and Endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		**20 working days****	

**Submission period is within thirty (30) days from the issuance date of the Notice of Deficiencies.*

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*