18. CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR VARIATION EXCEPT FOR VARIATIONS CLASSIFIED AS TURNED INITIAL APPLICATIONS AS PER FDA CIRCULAR NO. 2014-008)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Refer to FDA Circular No. 2014-008, Annex D Payment shall be on a per product, per change basis 1. Regular PACs, including change of capsule color Php500.00 + LRF 2. With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement Php500.00 + LRF 3. With FDA Clinical Review for additional indication. Php2,500.00 + LRF 4. With Subsequent Labeling Amendment per product strength. +Php 500.00+LRF 5. Change or addition of brand name Php2,500.00 + LRF + 510.00 (for each brand name proposed) 6. Shelf-life extension/reduction ...Php1,000.00 + LRF 7. Equivalent to Initial Registration, including Additional Route of Administration Unbranded Php10,000.00 + LRF Branded Php15,000.00 + LRF Monitored Release Status Php20,000.00 + LRF (for Three years) + Php20,000.00+ LRF (for additional Two years as per FDA Circular 2013-004) 8. Reclassification ....Php3,000.00 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MAJOR VARIATION (except Turned-Initial variation applications) FDA Circular No. 2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines AO No. 47-a, series of 2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products 3. Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) 4. Complete List of Documentary Requirements based on Annex C of FDA Circular No. 2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) 3.Proof of Payment based on Annex D of FDA Circular No. 2014-008 4.Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/Landbank FDAC *Personnel*
	4. Receives the application from FDAC and encodes/updates the database	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit

	5. Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	Day 2-21 20 working days	CDRR-CRR Unit *Personnel*
	6. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	Day 22 1 working day	LRD *Chief*
	7. Evaluates the application according to requirements and prescribed standards	None	Day 23-72 50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet with recommendations (from safety and efficacy evaluation, if applicable) and drafts certificate when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)	None	Day 72 1 working day	*FDRO I/II/III*

	For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 working days	*FDRO III*
	9. Prepares the final output document (Certificate/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	Day 113 1 working day	*FDRO I/II*
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 114 1 working day	*FDRO III*
	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day (per batch of applications)	*FDRO IV* *(Supervisor)*

	12. Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	Day 116 1 working day (per batch of applications)	*LRD Chief*
	13. Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	*CDRR* *Director*
	14. Encodes/Updates the Database and Endorses the final output document (Certificate/LOD) to the CDRR-Records Section	None	Day 118 1 working day (per batch of applications)	*CDRR-CRR* *Unit Personnel*
	15. Scans, barcodes, and emails the scanned copy of the Certificate/LOD to the client, updates the database and endorses the Certificate to the AFS-Releasing Section	None	Day 119 1 working day (per batch of applications)	*CDRR-Records Personnel*
4. Receives the Certification /LOD/letter	16. Releases the Certification/LOD to the client	None	Day 120 1 working day	*AFS* *Releasing Section Personnel*
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31.		**TOTAL:**	**120 working days**	