19. CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MINOR VARIATION – PRIOR APPROVAL 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
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 MINOR VARIATION (except Turned-Initial variation applications) FDA Circular No. 2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products 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 ASEAN Variation Guidelines 1. Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) 2. 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)	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
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

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	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
	5. Queuing time of the application before decking to evaluators	None	Day 2-21 20 working days	CDRR-CRR Unit *Personnel*
	6. Decks/ Assigns the application to the assigned evaluator	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*
If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet and drafts certification when the approval of the application is recommended			

	Prepares a worksheet and Letter ofs Disapproval (LOD) when the application does not merit an approval recommendation 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	None	Day 72 1 working day	*FDRO I/II/III*
	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 (Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	Day 113 1 working day	*FDRO II*

	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the	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)	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	None	Day 116 1 working day	*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 to the CDRR- Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*
	15. Scans and emails the scanned copy to the client; and endorses the final output document to the AFS Releasing Section		Day 119 1 working day (per batch of applications)	CDRR-Records Personnel
4. Receives the Certification /LOD/letter	16. Releases the Certification/LOD/Letter to the client	None	Day 120 1 working day	AFS Releasing Section Personnel
(Service 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**	