8. CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR AND MINOR VARIATION-PRIOR APPROVAL) VIA FACILITATED REGISTRATION PATHWAY (FRP)

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	:	Post-Approval Change/s: 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 Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF 8. Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA
(provided under Sec. IV.B. of Administrative Order No. 2020-0045, reiterated with necessary clarifications under Sec. V.A of FDA Circular No. 2022-004)

1. The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA;
2. The applicant may avail of the following submission pathways under FRP, subject to certain conditions.

a. Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
b. Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product application is within three (3) years from the date of approval of the RDRA/s.
c. The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.

3. The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
   a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
   b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
4. The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
5. The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
6. All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

1. Applications for RDRA/s post-approval changes
   a. A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s that approved the post approval changes.
   Note: The date of RDRA approval to be reflected in Annex B shall be the date the post-approval change/s was/were approved by the RDRA.
   b. Official approval letter or notification of the post-approval change/s from the identified RDRA/s.
   c. For changes and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product (categorized as major variation [MaV]-1 based on the ASEAN Variation Guideline for Pharmaceutical Products and as adopted through FDA Circular No. 2014-008 or any amendment or latest issuance thereafter), Assessment Report from each of the identified RDRA/s shall be required.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all

applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular. The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched. See checklist of requirements below for additional requirements.

CHECKLIST OF REQUIREMENTS FOR POST-APPROVAL CHANGES 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 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) 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 E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	2. Pre-assesses the completeness of the application and verifies the application if indeed for the abridged/verification review pathway for post-approval changes. 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	None		CDRR *Personnel*
2. 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. Decks/Assigns the application to the assigned evaluator of the Registration Section.	None	Day 3 1 working day	CDRR *Director*
	6. Evaluates the application according to requirements and prescribed standards	None	Day 4-18 15 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III*
If an electronic notice of deficiencies0 (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet and drafts Certificate of Product Registration (CPR) or Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		*FDRO I/II/III*
	7. Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 19-23 5 working days	FDRO III

	8. Prepares the final output document (CPR/ Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	Day 24 1 working day	FDRO I/II/III
	9. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 25 1 working day	FDRO IV (Supervisor)
	11. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 26 1 working day	LRD Chief
	12. Signs and approves the final decision	None	Day 27 1 working day	CDRR Director
	13. Encodes/Updates the Database and endorses the final output document (CPR/Certification/LOD/Letter) to the CDRR-Records Section	None	Day 28 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	14. Scans, barcodes the final output document (CPR/Certification/ LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 29 1 working day (per batch of applications)	CDRR-Records Personnel
3. Receives the CPR/Certification /LOD/Letter	15. Releases the CPR/ Certification /LOD/Letter to the client	None	Day 30 1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA Circular No. 2022-004).		**TOTAL:**	**30 working days**	