10. CERTIFICATE FOR POST-APPROVAL CHANGES OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

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 WHO Pre-qualified 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. V.B. of FDA Circular No. 2022-009)

1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure.

2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT).

3. The eligible product shall be the same as the product prequalified by the WHO/PQT.
a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT 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 WHO/PQT.

4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA Circular (FC) No. 2014-008, its amendment FC No. 2014-008-A, supplement FC No. 2016-017, and succeeding issuances for the same purposes.

5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.

GENERAL REQUIREMENTS

Documentary requirements:

1. Accomplished application form as per FC No. 2014-003, as prescribed in FA No. 2022-0001, subject to any future issuance providing for its amendment, repeal, or modification;
2. Letter of Request for Post-Approval Changes (Annex E);

3. The official post-prequalification variation approval document issued by the WHO/PQT; and
4. Documentary requirements following FC No. 2014-008 (Application Process and Requirements for Post-approval Changes of Pharmaceutical Products) and its amendment, FC No. 2014-008-A, or any future issuance providing for its repeal, further amendment, or modification.

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	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	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*

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 (CRR) Unit
	5. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section.	None	Day 3 1 working day	CDRR *Director*

	6. Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	Day 4-8 5 working days	FDRO I/II/III
	7. Evaluates the application according to requirements and prescribed standards	None	Day 9-15 7 working days	FDRO *I/II/III*

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 Certificate of Product Registration (CPR)/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*
	8. Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 16-20 7 working days	FDRO III
	9. Prepares the final output document (CPR/Certificate 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 or Certificate	None	Day 21 1 working day	FDRO I/II/III
	10. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		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 22 1 working day	FDRO IV (Supervisor)

	12. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 23 1 working day	LRD Chief
	13. Signs and approves the final decision	None	Day 23 1 working day	CDRR Director
	14. Encodes/Updates the Database and endorses the final output document (CPR/Certificate/LOD/Letter) to the CDRR-Records Section	None	Day 24 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	15. Scans, barcodes the final output document (CPR/Certificate/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 24 1 working day (per batch of applications)	CDRR-Records Personnel
3. Receives the CPR/Certificate/LOD/Letter	16. Releases the CPR/Certificate/LOD/Letter to the client	None	Day 25 1 working day	AFS - Releasing Section Personnel
	17. Notifies the WHO/PQT of the regulatory decision (CPR/Certificate/LOD/Letter)	None	Within Day 23-25	FDRO I/II/III
(Service is covered under FDA Circular No. 2022-009).		**TOTAL:**	**25 working days**	