FDA Circular
No. _____

SUBJECT: **Implementing Guidelines for Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) - Prequalified Drug Products and Vaccines**

I. RATIONALE

Republic Act No. 3720, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", as amended, and Republic Act No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations, declare that it is the policy of the state to ensure the safety, efficacy, and quality of drug supply in the country so as to protect the health of the Filipino people. FDA, as the national regulatory authority (NRA) in the country, together with the Department of Health (DOH), are tasked to ensure that there is (1) a constant supply of drugs, including vaccines, and (2) facilitated access to safe, effective, and quality drugs.

In 2013, World Health Organization (WHO) issued the initial collaborative review procedure under Annex 4 of WHO Technical Report Series (TRS) No. 981, 2013. In 2016, a revised procedure was issued under Annex 8 of WHO TRS No. 996. This was adopted as per Administrative Order No. 2020-0044: Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified.

Given the current resource constraints affecting drug regulation, collaboration and regulatory convergence with international organizations such as WHO, and other stringent regulatory authorities (SRAs) is necessary. In line with the efforts for collaboration, an Administrative Order has been issued to adopt the abovementioned Procedure.

The issuance of this Circular is to clearly define the rules and regulations in the implementation of the Collaborative Registration Procedure, and the activities that must be undertaken by the concerned stakeholders.

II. OBJECTIVES

This Circular aims to provide guidance on the Collaborative Registration Procedure (CRP) for WHO-prequalified drug products and vaccines for initial and monitored release registration.

III. SCOPE

This Circular shall apply to all FDA-licensed drug manufacturers and distributors (e.g. importers) of drug products which have been prequalified through the WHO.

This Circular shall not be applicable to drug products that shall avail other facilitated registration pathways.

IV. GUIDELINES

The FDA, as a participating National Medicines Regulatory Authority (NMRA) for the Collaborative Registration Procedure, hereby promulgates the following for the submission of an application for registration of a prequalified product through CRP.

A. Initial and Monitored Release Registration Process and Requirements

1. The FDA adopts the WHO CRP as a registration pathway, consistent with Good Regulatory Practices (refer to Annex A for process flow). Notwithstanding this, the FDA retains its prerogative to assess applications and apply judgements that consider benefits and risks as it applies to the Philippine context.

2. The applicant must ensure that the Manufacturer or Prequalification Holder has submitted the Appendix 2 of WHO TRS 996 (refer to Annex B of this Circular) of the adopted procedure, "*Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure",* to World Health Organization Prequalification Team (WHO/PQT) prior to submission of the registration application with FDA.

3. Submission of the registration application shall follow the existing process following the latest issuance of FDA. The applicant shall submit the following:
   a. Application form as prescribed by FDA for the registration of drug products
   b. Application dossier compliant with the existing requirements [e.g. Association of Southeast Asian Nations (ASEAN) – Common Technical Dossier (CTD) (ACTD), International Council on Harmonization (ICH) – CTD (ICH-CTD)], or WHO/PQT Dossier
   c. Country specific requirements such as:
      i. Foreign GMP clearance issued by FDA;
      ii. Labeling materials consistent with country-specific requirements;
      iii. Stability studies conducted under Climatic Zone IVb (hot and very humid) for applicable products;
      iv. Risk Management Plan (RMP) for pharmaceutical products under Monitored Release registration status; and
      v. Tabulated summary of WHO/PQT variation approvals prior to the registration application through CRP, obtained by the manufacturer/prequalification holder

4. Appendix 3, Part A of the adopted procedure (refer to Annex C of this Circular), *"Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health*

Organization (WHO)-prequalified pharmaceutical product or vaccine". In cases where the applicant company is not the original WHO PQ holder, the applicant company must submit an authorization letter that indicates agreement of the original WHO PQ holder, following the prescribed format in Appendix 3, Part A of WHO TRS 996 to the FDA.

5. Within fifteen (15) calendar days of receipt of the registration application by FDA, i.e., receipt by the Center for Drug Regulation and Research, the FDA shall pre-assess for the completeness of the dossier submission.

6. Applications that have acceptable submission shall be issued with the pre-assessment form with fees to be paid. The applicant shall endorse the proof of payment to the FDAC. The FDAC shall then endorse the application to CDRR.

7. The CDRR shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of the adopted procedure, "*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*".

8. Upon grant of access to the shared documents by WHO/PQT, the FDA is given a maximum of ninety (90) calendar days of regulatory time to evaluate the registration application using information provided by WHO, make a decision, and inform the applicant/importer. If, upon evaluation of the submitted documents, it is found that additional documents or further clarification is required to meet the appropriate standards for safety, quality, and efficacy, the applicant/importer shall be informed in writing. Regulatory time starts after a valid registration application following the CRP has been received and access to confidential information has been granted by WHO (whichever is later) and continues until the date of decision on the registration application. The regulatory time does not include the time granted to the applicant/importer to complete missing parts of the documentation, provide additional data or respond to queries raised by FDA.

9. Drug products approved through this scheme shall be given with a different set of registration number code from the drug products approved from the regular review process. Previous Certificate of Product Registration issued bearing the old registration number shall be reconstructed without fees to be issued with the new registration number code.

10. Within thirty (30) calendar days of issuing a regulatory decision to the applicant/importer, FDA shall inform WHO/PQT through Appendix 3, Part C of the adopted procedure, "*Notification of outcomes of national registration procedure by the NRA*".

FDA reserves the right to disapprove registration applications following the CRP if deemed necessary, and/or conduct/organize site inspections as needed. For disapproved registration applications, a detailed written justification shall be provided by FDA to the applicant and WHO.

B. Designated FDA Officers

FDA shall assign the appropriate Food-Drug Regulation Officers (FDROs) to coordinate with WHO/PQT for granting of access to confidential prequalification inspection reports and dossier assessment reports.

C. Fees

The appropriate fees as prescribed under existing regulations shall apply, including a Legal Research Fee (LRF), following A.O. No. 50 s. 2001. Refer to Annex D for the complete tabulation of Fees.

The FDA, from time to time, may prescribe changes in fees, which shall be promulgated in an appropriate regulation.

D. Accessibility

The adopted WHO CRP forms, checklist of requirements, and other information/updates shall be made accessible on the FDA Website.

V. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VI. EFFECTIVITY DATE

This Circular shall take effect fifteen (15) calendar days after publication in one (1) newspaper of general circulation and after submission to University of the Philippines, Office of the National Administrative Register (ONAR).

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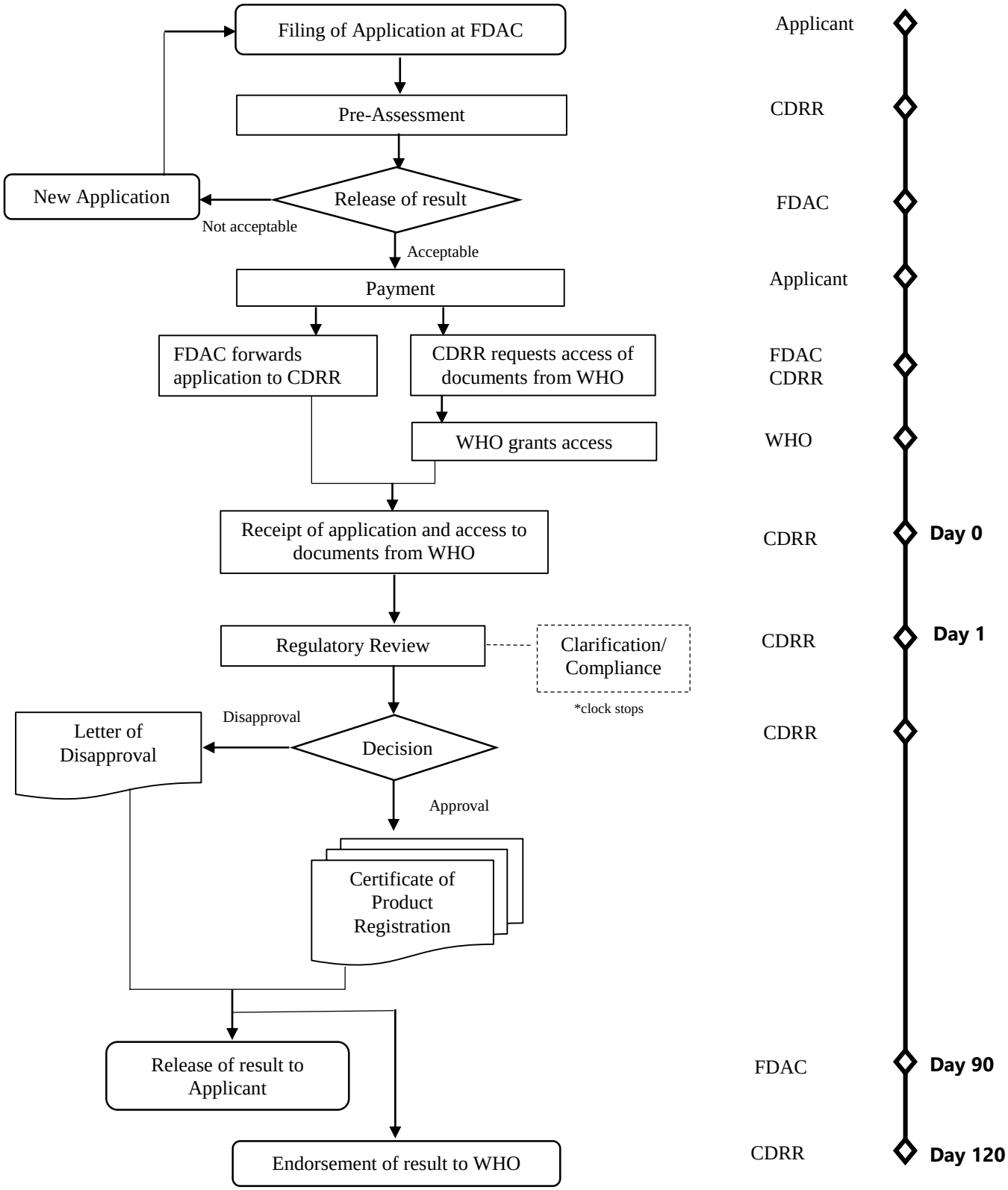
Director General

Keywords	Collaborative procedure, Collaborative review procedure WHO, FDA, Prequalified drug products
Related Issuances, laws, directives from other government agencies	Republic Act No. 3720, Republic Act No. 9711, Administrative Order No. 2013-0021, Administrative Order No. 2020-0044

ANNEX A

Application Process Flow Chart for Initial and Monitored Release Registration



**If the Regulatory Reviewers request for supplementary information from the applicant, the clock stops on the day the request is sent via email. Review will commence on the day the response is received.*

ANNEX B

WHO TRS 996 Appendix 2

Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure

ANNEX C

WHO TRS 996 Appendix 3, Part A

Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified pharmaceutical product or vaccine

ANNEX D

Fees and Charges

Application Type	Fees
Monitored Release (3 years validity)	
Registration	Php 20,000.00 + LRF
Clinical Review	Php 5,000.00 + LRF
Brand Name (if any)	Php 500.00 + LRF
Initial (5 years validity)	
Branded	Php 15,000.00 + LRF
Unbranded	Php 10,000.00 + LRF
Brand Name (if any)	Php 500.00 + LRF