Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Guidelines on Facilitated Registration of Drugs Products, Vaccines and Biologicals: Abridged Review, Verification Review, and Collaborative Procedure**

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. As the national regulatory authority (NRA) under the Department of Health (DOH), the Food and Drug Administration is tasked to ensure that there is a constant supply of drugs, and facilitate access to safe, effective, and quality drugs.

Republic Act No. 10747 entitled "Rare Diseases Act of the Philippines" states that the FDA shall prioritize the process of issuance of the Certificate of Product Registration (CPR) for Orphan Drugs.

Republic Act No. 11215 entitled "National Integrated Cancer Control Act" states that the FDA shall create streamlined process for licensing innovator and generic cancer medicine, subject to appropriate quality checks, being used for cancer treatment in other countries.

By virtue of the aforementioned Acts, to address the immediate need of access to safe, effective, and quality drugs by accelerating the national registration review and approval procedure, while ensuring sound regulatory assessments, this Order is hereby established.

II. OBJECTIVES

The general objective of this Administrative Order is to provide facilitated registration procedure and review process of drug products, including vaccines and biologicals.

Specifically, this Administrative Order aims to:

1. Provide registration procedures for market authorization holders (MAH) of drug products holding current approval from reference drug regulatory agencies and prequalification/ registration;
2. Participate in the global or regional collaborative procedures for accelerated registration;
3. Identify the reference drug regulatory agencies as the basis for an abridged and verification review registration procedure; and
4. Establish strategic assessment and evaluation process of drug products that already passed stringent regulatory approvals from foreign drug regulatory agencies.

III. SCOPE AND COVERAGE

This Order shall apply to all MAH of drug products holding current approval/s from reference drug regulatory agencies and/or registered under the collaborative registration procedures.

IV. DEFINITION OF TERMS

Abridged review – limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements while relying on prior assessment from reference drug regulatory agencies to inform the local decision. The review is based on complete assessment report, including question and answer (Q&A) documents, dossier including stability data.

Collaborative procedure – assessment process recognized by FDA through reliance, work-sharing, or joint reviews with other drug regulatory agencies, regional agencies or related organization.

Verification review – assessment process by which the submission has been evaluated and approved by at least two (2) reference drug regulatory agencies, the FDA only validates the submission and ensures that the product for local marketing conforms to the registration conditions as approved by the reference drug regulatory agencies.

Primary Reference Drug Regulatory Agency – one of the reference drug regulatory agency declared by the MAH as the primary reference agency from which the supporting documents will be submitted.

V. GENERAL GUIDELINES

A. The MAH may use the submission pathways for facilitated registration of their products.
B. The MAH for registration of a drug product shall be a holder of a valid License to Operate (LTO) and Good Manufacturing Practice (GMP) Certificate issued by the FDA.

C. The eligible MAH shall ensure that the drug product applied is the same as the product duly approved in the reference drug regulatory agencies or registered or prequalified under the collaborative registration procedure.
D. The FDA Center for Drug Regulation and Research (CDRR) shall evaluate, assess, and review documents submitted through this procedure.
E. Selected CDRR personnel shall be assigned to coordinate with the related organizations or regulatory agency in relation to the prequalification status and restricted access to inspection reports, assessment reports, dossier, and related documents.
F. The FDA shall provide and update the list of reference drug regulatory agencies that will serve as the basis for abridged and verification review.
G. Applications shall still be bound to the national regulations and requirements for submission and review of pharmaceutical products.
H. The FDA shall develop and issue implementing guidelines for the effective implementation of this Order.
I. Application through these pathways does not guarantee approval from the FDA.

VI. SPECIFIC GUIDELINES

A. Facilitated Registration Procedures

Applicant that will avail the facilitated registration shall select any of the facilitated registration procedures, subject to the applicability to their existing product dossiers.

1. Abridged Review
2. Collaborative Procedure
3. Verification Review

B. Eligibility

1. All the aspects of product quality including but not limited to formulation, manufacture, specifications, and shelf-life are identical to that of the currently approved by the primary drug regulatory agency or prequalified or registered through global or regional collaborative registration procedure. However, certain sections of the dossier shall still comply with current ASEAN and national requirements.
2. The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any reference drug regulatory agency due to quality, safety, or efficacy reasons.
3. The information on the proposed Package Insert (PI)/Patient Information Leaflet (PIL) should be identical to that of the approved by the reference drug regulatory agency with the addition of country-specific information stipulated in the current labeling requirements.
4. All documents must be in English.

C. Documentary Requirements

1. FDA Application Form for the registration of drug products & corresponding fees.

2. Registration requirements based on current guidelines for pharmaceutical products
3. Proposed labeling materials following the current labeling requirements.
4. Updated Summary of Product Characteristics (SPC).
5. Application dossier either in ASEAN Common Technical Document (ACTD) or International Council for Harmonization (ICH) Common Technical Document (CTD) identical to that of the submitted dossier approved by the primary reference drug regulatory agency.
6. Complete clinical and quality assessment reports, including the question and answer documents.
7. Assessment reports, and documents pertaining to post-approval changes or variations, if applicable.
8. Pharmacovigilance requirements such as Risk Management Plan (RMP) & Periodic Benefit-Risk Evaluation Report (PBRER), if applicable.
9. Declaration letter stating that the product's quality is identical to the currently approved by the primary reference drug regulatory agency.

D. Application Process

1. An application through a facilitated review procedure for registration is considered valid and final upon submission of complete requirements including payment of required fees and charges.
2. The evaluation of application shall be based on the completeness and accuracy of the submitted documents.
3. Any documents submitted under false pretenses, misrepresented (in whole or part) or otherwise deceptive shall subject the individuals and/or establishments involved shall be investigated, and appropriate charges may be filed, and penalties be imposed, if the circumstances so warrant.

E. Market Authorization

A CPR shall be issued to the MAH that complies with the documentary (technical and administrative) requirements and standards of safety, efficacy and quality based on existing FDA rules and regulations.

A registration number shall be assigned to the drug product whose product registration application has passed the evaluation and review process of the FDA.

F. Cancellation of CPR

1. Automatic Cancellation
   The registration of drug product will cease to be valid if the drug product is not placed on the market within three (3) years after the CPR has been granted or if removed from the market for three (3) consecutive years.

2. Voluntary Cancellation
   The MAH may apply for voluntary cancellation of its existing CPR by filing a formal notification with the FDA citing the reason thereof.

3. Cancellation and/or Revocation as a Penalty

The FDA shall impose the penalty of cancellation and/or revocation of CPR as per Book II, Article I, Sec. 4. Grounds for Disapproval of Application and Suspension or Cancellation of License, Registration or Authorization of the IRR of RA 9711.

The MAH shall remain to be accountable/liable for any violations committed and are subject to the penalties levied and administrative sanctions imposed by FDA.

G. Accessibility

The relevant forms, requirements for application, and the submission process shall be made accessible at the FDA website.

H. Responsibility of the MAH

The MAH is responsible in monitoring the quality, safety, and efficacy of its product. In case the product has been withdrawn for quality and safety reasons, the MAH shall immediately undertake the necessary measures, and shoulder incidental cost, in banning its sale and distribution, or its recall, withdrawal or seizure from the market, and its disposal in accordance with existing rules and regulation.

VII. REPEALING AND SEPARABILITY CLAUSE

Provisions in existing administrative orders, bureau circulars and memoranda inconsistent with this Administrative Order are hereby withdrawn, repealed and revoked accordingly.

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

VIII. EFFECTIVITY DATE

This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing to the University of the Philippines Law Center-Office of the National Administrative Register.

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Secretary of Health

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Related Issuances	Republic Act No. 3720, Republic Act No. 9711, Administrative Order No. 2013-0021
Keywords	Good reliance practice, facilitated registration procedure, abridged review, verification review, registration procedure, collaborative procedure, prequalification, reference drug regulatory agency