Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2022-004

16 JUN 2022

SUBJECT : **Implementing Guidelines on the Abridged and Verification Review Pathways for New Drug Registration Applications in accordance with Administrative Order No. 2020-0045 "Establishing Facilitated Registration Pathways for Drug Products including Vaccines and Biologicals"**

I. BACKGROUND

As pharmaceutical supply chains become more globalized and complex, regulatory oversight increases as well in complexity, on top of an increasing need for financial and technical resources. It is, therefore, strategic to establish regulatory reliance and cooperation practices among national regulatory authorities, in order to address individual regulatory gaps in a more efficient and effective manner. With the issuance of Administrative Order (AO) No. 2020-0045, entitled, "Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals", the Food and Drug Administration (FDA) recognized that instituting good reliance practices would be impactful toward facilitating access to drugs by producing more efficient regulatory mechanisms.

The World Health Organization, in its Technical Report Series No. 1033, Annex 10 – Good reliance practices in the regulation of medical products: high-level principles and considerations, defines reliance as *"the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible, and accountable for the decisions taken, even when it relies on the decisions, assessments, and information of others."*

In applying regulatory reliance, the FDA shall be streamlining its regulatory review to accelerate the registration process of drug products by leveraging against product regulatory assessments made by reference drug regulatory agencies (RDRAs). Simultaneously, strengthened post-marketing surveillance shall ensue and continuous improvement in building FDA's institutional capacity to effectively oversee innovative and complex advancements of drug products shall remain in the long term. Thus, pursuant to Republic Act (RA) No. 3720 as amended by RA No. 9711, the FDA hereby provides the implementation arrangements for the abridged and verification review pathways stipulated in AO No. 2020-0045 through this Circular as a pragmatic approach to institutionalizing regulatory reliance.

II. OBJECTIVE

This Circular aims to provide the implementing guidelines of AO No. 2020-0045 on the facilitated registration pathways (FRPs) through abridged review or verification review of new drugs, including vaccines and biologicals.

III. SCOPE AND COVERAGE

This Circular covers applications of new drugs including vaccines, and biologicals as defined in Section IV below, and shall apply to all licensed drug distributors intending to place in the local market or apply for post-approval changes of drug, vaccine, and biological products with existing and valid approval/s from RDRA/s.

This Circular only covers the abridged review and verification review types of FRP. For the collaborative procedure under AO No. 2020-0044 or the Adoption of the Collaborative Procedure for the Accelerated Registration of World Health Organization (WHO) – Prequalified Pharmaceutical Products and Vaccines, the implementing guidelines shall be covered by a separate Circular.

IV. DEFINITION OF TERMS

Abridged review refers to a 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 an RDRA to inform the local decision. The review is based on a complete assessment report, including question and answer documents, and the dossier including the stability data.

Verification review refers to an assessment process by which the submission has been evaluated and approved by at least two (2) RDRAs, and the FDA only validates the submission and ensures that the product conforms to the registration conditions, standards, and requirements as approved by the RDRAs.

A **new drug application** refers to a local registration application for a product that contains new chemical and/or biological entities proposed to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, new dosage forms, new dosage strengths, new routes of administration, and new indications. All generic products with FDA-approved equivalents shall not be considered new drugs.

Reference Drug Regulatory Agency (RDRA) refers to a national or regional regulatory agency for drugs, vaccines, and biologicals being relied upon by the FDA for a more efficient approach at arriving at a decision thereby improving and expediting quality assured, effective, and safe products.

Assessment Report refers to the complete, unredacted, or unedited copy of the assessment reports of the marketing authorization application and evaluated by the RDRA. The Assessment Report details and explains how the RDRA assessed the safety, quality, and efficacy data and information within the submitted dossier to inform its final decision on the regulatory action. The Assessment Report outlines the area of concerns, questions and answers, and clarifications which the RDRA raised and how these were addressed by the applicant and includes the product approval conditions, the final and approved product labeling, and all other annexes.

V. IMPLEMENTING GUIDELINES

A. Eligibility Criteria

The eligibility criteria provided under Sec. IV.B of AO No. 2020-0045, reiterated with necessary clarifications as follows, shall apply to applicants availing of the FRP:

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, subject to certain conditions.
    a. Abridged review may be availed when the drug product, vaccine, or biological has been approved by an 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.

B. Documentary Requirements

1. Applications for new drugs, vaccines, and biologicals
    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.
    b. Assessment Report from each of the identified RDRA/s.

c. A valid Certificate of Pharmaceutical Product (CPP) following the WHO Certification Scheme or its equivalent from the identified RDRA/s. If the product is not marketed in the jurisdiction of the identified RDRA/s, then a valid CPP or its equivalent from any of the RDRA/s as listed in Annex A may be provided.
d. Complete International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines.
e. A report of stability studies conducted under climatic Zone IVB (hot and very humid), with the required minimum time period covered by data at submission, the minimum number of batches, and storage conditions for accelerated and long-term conditions shall be provided unless otherwise justified.
f. Proposed Package Insert/Patient Information Leaflet identical to that approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.

2. 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.

C. Review and Evaluation

1. The abridged review or verification review shall be based on a limited independent assessment of specific parts of the dossier. The complete Assessment Report/s, including all annexes, and the dossier including the stability data shall be reviewed and evaluated. Suitability of use under local conditions and regulatory requirements while relying on the prior assessment/s of the RDRA/s shall be assessed. The FDA may request additional supporting documents, as deemed necessary, to ensure the safety, efficacy, and quality of the product intended for registration.
2. The FDA shall consider the benefits and risks as they apply to the Philippine context based on the available data provided by the applicant.
3. The FDA may consider seeking opinions from clinical experts as necessary.

D. Timelines

Type of Application / Pathway	Timeline
Abridged Review	not more than 45 working days
Verification Review	not more than 30 working days
Post-approval change/s	

The turnaround time shall start after receipt of the proof of payment with the complete application dossier.

These timelines are not applicable to registration applications of reproductive health products which are required to undergo the complete process stipulated in the Implementing Rules and Regulations of Republic Act No. 10354 or the Responsible Parenthood and Reproductive Health Act of 2012.

VI. FEES

The appropriate fees as prescribed under existing regulations shall apply, including a Legal Research Fee (LRF), following AO No. 50 s. 2001 or any amendment or latest issuance thereafter.

VII. PROCESSING OF PENDING APPLICATIONS

All pending applications which qualify for Abridged Review or Verification Review, and which were received on or after 30 October 2020, the effectivity of AO No. 2020-0045, if so desired, shall submit the additional requirements as described under Section V. B of this Circular.

VIII. PENALTY CLAUSE

The applicable penalties under Republic Act No. 9711 and its Implementing Rules and Regulations and other laws shall apply for any violations of this Circular or of AO No. 2020-0045.

IX. IMPLEMENTATION REVIEW

The FDA shall conduct a review of the implementation of this Circular after a period of five (5) years from its effectivity or earlier as needed.

X. SEPARABILITY CLAUSE

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

XI. EFFECTIVITY

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

By Authority of the Secretary of Health:

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

20210825142203

ANNEX A

List of Reference Drug Regulatory Agencies (RDRAs)*

1. Therapeutic Goods Administration (TGA) – Australia
2. Federal Agency for Medicines and Health Products (FAMHP) – Belgium
3. Health Canada (HC) - Canada
4. European Medicines Agency (EMA) - European Union
5. French National Agency for Medicines and Health Products Safety (ANSM) - France
6. Federal Institute for Drugs and Medical Devices (BfARM) – Germany
7. Paul-Ehrlich-Institut (PEI) – Germany
8. Italian Medicines Agency (AIFA) – Italy
9. Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
10. Medicines Evaluation Board (MEB) – Netherlands
11. Health Sciences Authority (HSA) – Singapore
12. Swiss Agency for Therapeutic Products (Swissmedic) - Switzerland
13. Medicines and Healthcare Products Regulatory Agency (MHRA) - United Kingdom
14. US Food and Drug Administration (USFDA) – United States of America

List of RDRAs for Veterinary Drug Products**

1. European Commission – European Union
2. European Medicines Agency (EMA) – European Union
3. International Federation for Animal Health - Europe (AnimalhealthEurope) representing industry – European Union
4. Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) – Japan
5. Japanese Veterinary Products Association (JVPA) representing industry – Japan
6. US Department of Agriculture (USDA) – Center for Veterinary Biologics (CVB) - United States of America
7. US Food and Drug Administration (USFDA) – Center for Veterinary Medicine (CVM) - United States of America

Note: The list may be updated at any time as determined by FDA.

* *Selection criteria include the founding members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), WHO Listed Authorities (WLAs) for medicines and vaccines, and other regional and national regulatory authorities performing or operating at maturity level 4.*

** *Selection criteria include the principle parties to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and members of its steering committee.*

ANNEX B

Sworn Assurance

I, (name of Head of Regulatory Office), (legal age), (citizenship), resident of (address), after being sworn according to law, hereby depose and state:

1. I am the Head of the Regulatory Office of (Name of Applicant Company) with business address at (address).
2. I am applying for the issuance of a (Certificate of Product Registration or Variation) of the (name of product) under a Facilitated Pathway Review under AO No. 2020-0045.

3. That the product being applied, including but not limited to the composition/ formulation, strength, manufacturing of finished product and active pharmaceutical ingredients, specifications, product information, and others, at the time of the submission, is the same in all respects as the product approved by the following RDRA/s:

RDRA	Date of RDRA approval
1. 2. . . .	1. 2. . . .

4. The documents submitted to the RDRA are in accordance with the requirements of ICH/ACTD, and if not, I hereby submit the necessary technical documents to comply with the dossier requirements and format following existing guidelines.

5. 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.

6. That there is full compliance with the eligibility requirements provided under AO No. 2020-0045, and all data and information submitted in connection with this application as well as other submissions in the future are true and correct and reflect the total information available.

7. I understand that the Philippine Food and Drug Administration (FDA) may verify through both government and private entities the authenticity of all the information and documents submitted. I fully consent and authorize the Philippine FDA to conduct such verification for purposes of evaluation of my application.

IN WITNESS WHEREOF, I have hereunto set my hand this (date) in (city).

(Name of Head of Regulatory Office)
Affiant

SUBSCRIBED AND SWORN to before me this _____ at _____, Philippines.

NOTARY PUBLIC

Doc. No.
Page No.
Book No.
Series of