Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. **2022-004-A**

15 FEB 2024

SUBJECT : **Amendment to FDA Circular No. 2022-004 entitled "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" to include Generic Drug Registration Applications and update the list of Reference Drug Regulatory Agencies**

In the continuous effort to streamline regulatory processes and adopt good reliance practices in the Food and Drug Administration (FDA) pursuant to Republic Act (RA) No. 3720 or the Food, Drug, Cosmetic Act, as amended by RA No. 9711 or the FDA Act of 2009, in relation to RA 11223 or the Universal Healthcare Act, and to RA No. 11223 or the Ease of Doing Business and Efficient Government Service Delivery Act of 2018, Administrative Order (AO) No. 2020-0045, entitled "Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals" was issued. The objective in the issuance of the AO is to improve the drug registration process through facilitated pathways, resulting in the timely access of drug products.

To effectively institutionalize AO No. 2020-0045, phase implementation approach prioritizing new drug products was provided through the issuance of FDA Circular (FC) No. 2022-004 entitled "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.'"

Ancillary to the effective institutionalization of AO No. 2020-0045 is the strict adherence to international standards to achieve confidence in the Reference Drug Regulatory Authorities (RDRAs). Thus, selection criteria for RDRAs to include operation at maturity level (ML) 4, per assessment by the WHO global benchmarking, was set by the FDA. After the issuance of FC No. 2022-004, several other National Regulatory Authorities (NRAs) have achieved ML 4 status and are therefore qualified as RDRAs of the FDA. Moreover, non-governmental organizations representing the industry have met the criteria and have been included in the list of RDRAs for veterinary drug products. However, it should be noted that these organizations, while meeting the criteria, do not hold the status of NRAs in their respective jurisdictions. Consequently, an update to the lists in Annex A of FC No. 2022-004 is imperative to apply these necessary changes.

Having established internal work procedures and efficient implementation of the facilitated review pathways for new drug applications, extending the scope of the implementing guidelines to cover generic drug applications, which constitute a substantial portion of the total received applications by the FDA, and updating the list of RDRAs from where assessment can be relied upon, are imperative to ensure that there is adequate market access to all drug products including generic drugs.

Accordingly, the following sections of FDA Circular No. 2022-004 are hereby amended:

Section II. Objective is hereby amended to read as:

> *"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* ***and generic*** *drugs, including vaccines and biologicals."*

xxx xxx xxx.

Section III. Scope and Coverage is hereby amended to read as:

> *"This Circular covers applications of new* ***and generic*** *drugs including vaccines, and biologicals as defined in Section IV below, and shall apply to all licensed drug* ***manufacturers, traders, and*** *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."*

xxx xxx xxx.

Section IV. Definition of Terms is hereby amended to include the following definitions:

> "Generic Drug shall refer to a drug product that has the same active pharmaceutical ingredient as the innovator drug, and with the same dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, and is not covered by patent protection. This drug is labeled by their international nonproprietary or generic name and may or may not have brand names."

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Section V. Implementing Guidelines is hereby amended to read as:

A. Eligibility Criteria

1. *xxx xxx xxx.*

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.
   b. Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs.

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B. Documentary Requirements

1. *Applications for new* ***and generic*** *drugs, vaccines, and biologicals*

xxx xxx xxx

In addition to the foregoing requirements for applications for new ***and generic*** *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.

Annex A is hereby amended to update the List of Reference Drug Regulatory Agencies (RDRAs) to include the following:

15. ***Ministry of Food and Drug Safety (MFDS) – Republic of Korea***
16. ***Saudi Food and Drug Authority (SFDA) – Saudi Arabia***

Additionally, Annex A is also hereby amended to update the List of RDRAs for Veterinary Drug Products to delist the following:

3. *International Federation for Animal Health - Europe (AnimalhealthEurope) representing industry – European Union*
5. *Japanese Veterinary Products Association (JVPA) representing industry – Japan*

All other provisions of FDA Circular No. 2022-004 not affected by this issuance are maintained and in effect. The eligibility criteria established under AO No. 2020-0045 and reiterated in FC No. 2022-004 shall be deemed applicable to generic drug product applications and be strictly complied with.

This Circular shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines Law Center-Office of the National Administrative Register (UP-ONAR).

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Director General

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