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

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

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In the continuous effort to streamline regulatory processes and adopt good reliance practices in the Food and Drug Administration (FDA), the Department of Health (DOH) Administrative Order (AO) No. 2020-0045, entitled "Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals" was issued. This Order intends to improve the drug registration process through facilitated pathways, as such, resulting to timely access to drug products.

To effectively institutionalize AO No. 2020-0045, phase implementation approach prioritizing new drug products is 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.'"

In addition, since strict adherence to international standards is critical to achieve confidence in the reference drug regulatory authorities (RDRAs), FDA has set the selection criteria for RDRAs to include operation at Maturity Level (ML) 4 as assessed by the WHO through their global benchmarking. After releasing the list of RDRAs through FC No. 2022-004 Annex A, more NRAs has achieved ML 4.

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 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,

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

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III. SCOPE AND COVERAGE

*"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 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."*

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IV. DEFINITION OF TERMS

Additional term under Section IV. Definition of Terms:

"Generic Drug shall refer to a drug product created to be the same as the reference drug product in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate interchangeability, which means that a generic drug works in the same way and provides the same clinical benefit as its reference drug product."

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V. IMPLEMENTING GUIDELINES

Revisions under Item no. 1 and Paragraph 1 of Section V.B. Documentary Requirements:

B. Documentary Requirements

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

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*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.*

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ANNEX A

Additional entries under List of Reference Drug Regulatory Agencies (RDRAs):

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

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All other provisions of FDA Circular No. 2022-004 not affected by this issuance are maintained and in effect.

This Circular shall take effect fifteen (15) 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).