FDA CIRCULAR
No. 2023-003-A

0 3 APR 2024

SUBJECT : **Amendment to FDA Circular No. 2023-003, entitled, "Guidelines on the Filing and Submission of Acceptable Variations on Protocols and Non-standard Protocols for the Review and Pre-Approval by the Food and Drug Administration Prior to the Conduct of Bio-efficacy Test Studies of Household Pesticides for the Purposes of Securing a Certificate of Product Registration"**

I. RATIONALE

On 3 February 2023, the FDA Circular No. 2023-003 was issued with an aim to improve the regulatory compliance and regulatory efficiency by facilitating the review of non-standard and modified bio-efficacy test protocol through a pre-approval scheme. The test protocols shall have sufficient and compelling justification to ensure soundness of the method and the reliability of product data to support product claims. A reduction in the rate of disapprovals on the product registration with bio-efficacy related concerns is anticipated as a result of the implementation of the policy.

A review of the initial implementation of the proposed policy revealed inconsistencies in the application process and documentary requirements in FDA Circular No. 2023-003, which may cause unharmonized appreciation of the said guidelines among the regulator and stakeholders. Thus, this Circular is hereby issued to address the need to update the said guidelines, by way of an amendment, in order to provide clarity and updates.

II. SPECIFIC GUIDELINES

A. To amend **Section V(A). Filing of an application**, to be read as follows:

"**A. Filing of Application**

Each application shall contain a single protocol which is a modification of an existing protocol or a non-standard protocol. An application shall be filed following the procedure outlined in the **updated Annex B.** An application shall be considered final upon submission of complete requirements, following pre-assessment, including payment of the required fees and charges. Incomplete applications shall be returned to the applicant.

A successful filing following pre-assessment shall not be construed as an approval of the application, wherein the comprehensive evaluation for correctness and compliance with administrative and technical standards is performed in the evaluation step."

B. To amend **Section B. Documentary Requirements,** to be read as follows:

"B. Documentary Requirements

1. Updated Letter of Intent (Annex D)[1]
2. Valid LTO
3. Copy of official receipt
4. Test Protocol
The test protocols shall contain the information as listed in Annex C."

III. SEPARABILITY CLAUSE

The provisions of this Circular are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

IV. REPEALING CLAUSE

This Circular hereby amends the pertinent provisions of FC No. 2023-003. All other administrative issuances, bureau circulars and memoranda and other regulations inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

V. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines Law Center Office of the National Administrative Register.

DR. SAMUEL A. ZACATE
Director General

[1] A template is hereby prescribed (see annex D) in order to allow the identification of the application and the reason for utilizing the non-standard bio-efficacy protocol. The template consolidates the previous requirements in FDA Circular No. 2023-003, specifically, the letter of intent and Integrated Application Form (IAF).