CENTER FOR COSMETICS AND HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES REGULATION AND RESEARCH (CCHUHSRR)

Virtual Consultation: Proposed issuance *"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"*
5 August 2022, 10:00AM to 11:30AM
via Google meet

I. Call to Order: The consultation started at 10:00AM with Mr. Kean Ruzzel M. Corales presiding.

II. Highlights:

Agenda	Highlights of the Discussion
1. Opening remarks by Engr. Ana Trinidad F. Rivera, MSc	● Background on the proposed policy ● FDA's mandate ○ To ensure the safety, efficacy and quality of products in the market.
2. Presentation of the proposed policy by Mr. Kean Ruzzel M. Corales	A presentation on the following was made by the speaker: ● Legal basis of the issuance ○ DOH AO No. 2019-0008 ○ DOH AO No. 50 s. 2001 ○ RA 11032 ● Objective of the issuance ○ Improve the regulatory compliance of pesticide registration and facilitate establishment of a pathway for the review and pre-approval of non-standard and modified bio-efficacy test protocols ● Salient features of the proposed policy ○ Applicant must be a holder of a valid LTO as HUP establishment issued by FDA. ○ All HUP shall preferably be tested in accordance to Annex A "*List of Bio-efficacy Test Studies with accepted Test Protocol/s*" ○ MAH utilizing a non-standard and modified protocol for HUP registration shall submit the said test protocol to the FDA for review and approval. ○ Applications for the pre-approval of non-standard and modified bio-efficacy test protocols shall be filed following the procedure of the proposed policy. ○ Re-using of pre-approved bio-efficacy protocol is allowed. Provided, the product type, intended use and manner of use shall be similar to as the previously approved bio-efficacy protocol, and

	the MAH of the pesticide registration shall be the same.
3. Presentation of consolidated comments by Ms. Gabrielle S. Gabriel	A presentation on the following was made by the speaker: ● Consolidated comments from the Draft for comments posted from 29 June 2022 to 29 July 2022. ● Feedback on the consolidated comments (Annex B)
4. Listening session for stakeholders facilitated by Mr. Kean Ruzzel M. Corales and Ms. Karen Cristy L. Panis	A listening session for stakeholder comments was facilitated in the following manner: ● Pre-registered participants, who signified their intent to share their comments were included in the pool of speakers during the listening session. ● Due to time constraints, a limited number of speakers were accommodated. ○ 10 speakers given 3 minutes each ● All those who were not called to speak were requested to submit their written comments up to Monday (end of business day). ● Based on the listening session and comments received until Monday (8 August 2022) EOB, comments will be collated and reviewed, then feedback will be provided through e-mail or the FDA website.
5. Presentation of the next steps on policy development by Ms. Gabrielle S. Gabriel.	The following were discussed by the speaker: ● The listening session and submitted comments will be reviewed and to incorporate meritable recommendations. ● Feedback from the listening session and submitted comments will be provided through e-mail or the FDA website. (Annex C) ● The finalized guideline will secure clearances and will be endorsed for approval. ● Expected issuance and dissemination: 2nd Semester of 2022
6. Closing remarks by Ms. Ofelyn C. Cabrido, RPh, MGM	● Wrapped up the session and expressed gratitude on behalf of the Center for the stakeholders' active participation in improving the proposed policy.

III. Adjournment: The consultation was adjourned at 11:16AM

Prepared by:

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Checked by:

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Approved by:

Engr. Ana Trinidad F. Rivera, MSc
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