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

Virtual Consultation: Proposed issuance *"Updated Guidelines on Product Information File (PIF) for Cosmetic Products Repealing FDA Circular No. 2018-001 'Reiterating the Mandatory Implementation of Article 8 of the ASEAN Cosmetic Directive, Product Information'"*
07 September 2022, 1:00 PM to 3:00 PM
via Google meet

I. Call to Order: The consultation started at 1:00 PM with Ms. Laarni M. Pagcaliwagan 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 o To ensure the safety, efficacy and quality of products in the market.

2. Presentation of the proposed policy by Ms. Laarni M. Pagcaliwagan	A presentation on the following was made by the speaker:
	• Legal basis of the issuance
	  o DOH AO No. 2005-0015
	  o DOH AO No. 2005-0025
	• Relevant issuance
	  o FDA Memorandum Circular No. 2015-011
	• Existing issuances
	  o FDA Circular No. 2018-001
	  o FDA Advisory No. 2022-0383
	• Objective of the issuance
	  o Improve the regulatory compliance to PIF requirements as set forth by the ACD and establish an updated PIF guidelines in the context of evolving digital technology and pandemic resiliency
	• Salient features of the proposed policy
	  o PIF as a mandatory requirement for notified cosmetic products
	  o The outlined responsibilities of the Market Authorization Holders (MAHs)
	  o Arrangement and maintenance of a PIF
	  o Information confidentiality
	  o Conduct of PIF Audit
	  - Types of Audit: Routine & Ad hoc PIF Audit
	  - Sites of Audit: On-site & Off-site PIF Audit (Remote & Desktop PIF Audit)
	  - Deficiencies: Critical, Major & Other deficiencies

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 21 July 2022 to 11 August 2022. ● Feedback on the consolidated comments (Annex A)
4. Listening session for stakeholders facilitated by Ms. Laarni M. Pagcaliwagan 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. o 15 speakers given 3 minutes each ● All those who were not called to speak were requested to submit their written comments up to Friday (end of business day). ● Based on the listening session and comments received until Friday (09 September 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 B) ● 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 2:50 PM

Prepared by:

Laarni M. Pagcaliwagan
FDRO I, CCHUHSRR

Checked by:

Ofelyn C. Cabrido, RPh, MGM
Chief, FDRO V, CCHUHSRR

Approved by:

Engr. Ana Trinidad F. Rivera, MSc
Director IV, CCHUHSRR