



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

3rd Virtual Dialogue on the Implementation of FDA Circular No. 2020-025
22 November 2021, 8:30AM to 12:00NN
via Webex by Cisco

- I. Call to Order:** The meeting started at 08:30 AM with Ms. Chelsea Jazmine S. Sangalang presiding.
- II. Attendance:** See attached Annex A - *Attendance Sheet*
- III. Highlights:**

Agenda	Issues & Concern	Action Taken/Response
1. Opening Remarks by Engr. Ana Trinidad F. Rivera, MSc.	<ul style="list-style-type: none"> • The opening remarks highlighted the importance of Household/Urban Hazardous Substances (HUHS) Regulation • Refer to Annex B - <i>Updates on HUHS</i> for a copy of the whole presentation. 	Noted by stakeholders
2. Presentation on CCHUHSRR Implementation of FDA Circular No. 2020-025 by Ms. Cheryl Lynn C. Tan and Ms. Ma. Christina D. Ledesma	<p>The presentation discussed:</p> <ul style="list-style-type: none"> • Brief recap of the HUHS regulation timeline • HUHS Plan <ul style="list-style-type: none"> ○ 2-Year Transitory Period Extension from 01 January 2022 to 31 December 2023 <ul style="list-style-type: none"> ▪ NOT APPLICABLE to licensing of establishments; effective 01 January 2022, LTO is mandatory for HUHS establishments ▪ APPLICABLE to product registration; effective 01 January 2024, CPR is mandatory for all HUHS products in the market ▪ APPLICABLE to HUHS product labels where only the minimum label information shall be required during product registration; effective 01 January 2024, full compliance to Annex J of FDA Circular No. 2020-025 including the GHS label elements is mandatory for HUHS product labels. 	Noted by stakeholders



	<p>Note: The transitory period shall also serve as the exhaustion period of non-compliant HUHS product labels.</p> <ul style="list-style-type: none"> o Incorporation of Notice of Deficiencies (NOD) Step in the application process for HUHS Certificate of Product Registration (CPR) <ul style="list-style-type: none"> ▪ more stringent pre-assessment that checks for completeness, correctness and consistency of information / documents ▪ evaluation that checks/assess product quality, safety and efficacy of the product <p>Note: There is a delay in the planned implementation of the NOD step. An official FDA advisory will be issued to announce its launch in the FDA e-Portal.</p> <ul style="list-style-type: none"> o Information, Education & Communication Materials <ul style="list-style-type: none"> ▪ Guide Manuals for Stakeholders ▪ Improved Video Walkthrough Tutorials <ul style="list-style-type: none"> ● Proposed amendments to FDA Circular No. 2020-025 in order to clarify or provide guidelines on: <ol style="list-style-type: none"> a. Ready-to-Use (RTU) vs For Professional Use product category b. HUHS products also classified as HUP c. HUHS products classified as GHS Category 1 d. CMR ban e. HSR No XXXX in product label f. Child-Resistant packaging g. Substantiation of claims h. Substantiation of disinfection claims i. Manufacturing and expiration date on product label and substantiation of claimed shelf-life <ul style="list-style-type: none"> ● Refer to Annex C - <i>3rd Virtual Dialogue on the Implementation of FDA Circular No. 2020-025</i> for a copy of the whole presentation. 	
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3. Discussion – Q & A	<ul style="list-style-type: none"> The collated questions during the virtual dialogue and their corresponding answers will be posted on the FDA website in the coming days. 	HUHS Team
4. Closing Remarks by Ms. Ofelyn C. Cabrido, RPh, MGM	<ul style="list-style-type: none"> The closing remarks highlighted the Center’s appreciation for the HUHS Industry’s participation to the 3rd Virtual Dialogue on the Implementation of FDA Circular No. 2020-025 	Noted by stakeholders

IV. Adjournment: The meeting was adjourned at 12:00 NN

V. Schedule of Next Meeting: To be announced.

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