Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAY 17 2024

ADMINISTRATIVE ORDER
No. 2024 - 0008

SUBJECT: **Guidelines on the Licensing of Establishments Engaged in Refilling Activity of Certain Cosmetics and Household/ Urban Hazardous Substances (HUHS) Products**

I. RATIONALE

Over the years, manufacturing companies responsible for the production of cosmetics and health products have produced much innovation to the market, improving customer comfort with concurrent increase in mass production. One of these innovations is the single use plastics which have revolutionized product packaging, reusability and ease of use. Improper waste disposal and general misuse, however, resulted in environmental deterioration due to single use plastic proliferation.

Calls for the mainstreaming of refilling stations for certain cosmetic and household/urban hazardous substances (HUHS) products as a means to address this emerging environmental issue have been raised for immediate action by the government. Consequent to this, there is a need to ensure that in pursuit of such activities, the production and distribution of such products strictly comply with regulatory standards, which ultimately aim to ensure consumer safety.

Republic Act (RA) No. 3720 and RA No. 9711, along with their respective amendments and the Implementing Rules and Regulations (IRR), align with Department of Health (DOH) Administrative Order (AO) No. 2020-0017, which outlines unified licensing requirements. Additionally, these adhere to DOH AO No. 2005-0015, adopting the Association of Southeast Asian Nations (ASEAN) Cosmetic Directive, and the Food and Drug Administration (FDA) Circular No. 2020-025, providing guidelines for HUHS establishments and products, and further supporting the goals of the Asia-Pacific Economic Cooperation (APEC) in its drive to promote a circular economy.

This Order is hereby issued to provide guidelines on the regulation of establishments engaged in the refilling activity of regulated health products under the jurisdiction of the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), specifically certain cosmetic and HUHS products.

II. OBJECTIVE

This Order aims to establish guidelines on the licensing of establishments engaged in the refilling activity of cosmetic and HUHS products under the jurisdiction of the FDA.

III. SCOPE OF APPLICATION

This Order shall apply to establishments, including refilling stations, engaged in the refilling activity of cosmetic and HUHS products covered herein for refill.

However, this shall not cover regulations over household/urban pesticides and toys and childcare articles.

IV. DEFINITION OF TERMS

For purposes of implementing this Order, the following terms shall be referred to as:

A. **Bulk Product** - refers to any product which has completed all processing steps, up to but not including, final packaging.

B. **Certificate of Product Notification** - refers to the authorization issued by FDA to cosmetic establishments upon acknowledgement of an application for notification of cosmetic products prior to engaging in marketing, importation, sale, offer for sale, distribution, transfer, promotion, advertisement, and/or sponsorship thereof.

C. **Certificate of Product Registration** - refers to the authorization issued by FDA upon the approval of an application to register an HUHS product after evaluation of its safety, efficacy and quality, prior to engaging in marketing, importation, sale, offer for sale, distribution, transfer, promotion, advertisement, and/or sponsorship thereof.

D. **Cosmetic** - refers to any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting them or keeping them in good condition.

E. **Household/Urban Hazardous Substances** - refers to (1) Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizers, agricultural pesticides, and agricultural insecticides and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like; (2) Any substance which the FDA finds to be under the categories enumerated in paragraph one (1) of this section; (3) Any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard. For this purpose "*toys and other articles intended for use by children*" shall refer to those toys and articles specified to be for children less than fourteen (14) years of age; and (4) The term '*Household/urban Hazardous substance*' shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuel when stored in

containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph 1 of this section, by reason of bearing or containing such harmful substances described therein.

F. **License to Operate** - refers to the authorization issued by the FDA to an establishment to grant permission to undertake a trade or carry out a business activity, such as manufacturing, importation, exportation, sale, offering for sale, distribution, or transfer of health products.

G. **Refiller** – refers to a licensed cosmetic and/or HUHS establishment engaged in the refilling of bulk cosmetic and/or HUHS products into smaller quantities in a separate container, which may include labeling and stickering, with the end view of sale of the product directly to the general public.

H. **Refilling** – refers to a manufacturing activity performed by a certified and trained person of the cosmetic and/or HUHS Refiller in a refilling station, where bulk products manufactured are delivered as finished goods directly to the general public, such that the bulk cosmetic and/or HUHS products are used and purchased to replenish appropriate containers at the point of sale.

I. **Refilling Station** – refers to the branch office of the cosmetic and/or HUHS refiller, including outlets, and mall kiosks, where the refilling activity takes place.

Other terms herein used shall have the same meaning as defined in RA No. 9711 and its Implementing Rules and Regulations (IRR), and related laws and regulations.

V. GENERAL GUIDELINES

A. Only FDA-licensed cosmetic and/or HUHS establishments shall be allowed to engage in refilling activity/ies of cosmetic and/or HUHS products.

B. All FDA-licensed Cosmetic and/or HUHS establishments engaged in refilling activity/ies of cosmetic and/or HUHS products shall apply for a major variation application to add the refilling activity to their respective Licenses to Operate (LTO).

C. All FDA-licensed cosmetic and/or HUHS Refiller with approved major variation of refilling activity shall subsequently apply for a major variation to add each refilling station. A single Cosmetic and/or HUHS Refiller shall be allowed to have multiple refilling stations, provided that the Refiller and the refilling stations are a single establishment or a single legal entity. Engaging in subcontracting or franchising of the refilling activity shall be prohibited.

D. Cosmetic and/or HUHS refiller, including all refilling stations, shall be subject to monitoring and inspection by the FDA Regional Field Offices prior to engaging in refilling activity, and within the validity period of its LTO.

E. The LTO for the cosmetic and/or HUHS refiller shall list all refilling stations of the establishment conducting the refilling activity. Thus, a copy of the LTO, including the page bearing the address of the refilling station, shall be posted conspicuously in each refilling station. Additionally, copies of the Certificates of Product Notification (CPN) and/or the Certificates of Product Registration (CPR) of the products for refill shall be available and accessible in the refilling station carrying such products.

F. Only duly-authorized cosmetics and/or HUHS products shall be allowed for refill. Bulk products and refilled products shall bear the necessary labeling information as provided in these guidelines. Cosmetic and HUHS establishments shall ensure that the appropriate CPN for the bulk cosmetics for refill and CPR for the bulk HUHS products for refill shall be secured prior to applying for an authorization to engage in refilling activities.

G. Refilling activities shall be performed within the refilling station by trained personnel employed by the cosmetic and/or HUHS establishment, following procedures consistent with standards on good practices (GxP). Additionally, each refilling station and its activities shall be monitored by the Qualified Person of the establishment. Appropriate and adequate recordkeeping shall be ensured by the establishment and all refilling stations. These documentation and records shall be made readily available and accessible to the FDA for the purposes of LTO application, inspections, and post-marketing surveillance (PMS).

H. The Qualified Person shall comply with all administrative and technical requirements for authorization application set by the FDA, and the establishment's or Market Authorization Holder's post-approval obligations. He/she shall likewise ensure at all times his/her availability during inspection of the establishment, including its refilling stations, and if applicable, in all PMS activities to be conducted by the FDA such as, but not limited to, product information file audits.

I. Cosmetic and/or HUHS establishments, including its refilling stations, shall continuously comply with existing FDA laws, rules, regulations, and standards.

J. Existing standards, rules, and regulations for cosmetic and HUHS products shall still apply to refilled products.

VI. SPECIFIC GUIDELINES

A. Specific Cosmetics and HUHS Products for Refill

Only specific cosmetics and HUHS products determined and listed by FDA shall be allowed for refill. Such product listing shall be issued separately and updated regularly through corresponding FDA Circulars.

The refilled products of these specific Cosmetic or HUHS products, however, shall not be allowed for re-sale.

B. Application for License to Operate

All cosmetic and/or HUHS establishments engaged in refilling activities shall secure a License to Operate (LTO) and its variations from the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) of the FDA, prior to the conduct of refilling activity/ies, and shall follow the applicable licensing procedure as prescribed in existing issuances.

C. Compliance with Good Practices Quality Guidelines for Purposes of Refilling Activity

The FDA shall provide "good practice" (GxP) quality guidelines for cosmetics and HUHS refiller and its refilling stations to develop their own internal quality management system and procedures. Such guidelines shall be separately issued through appropriate FDA issuances. Compliance with GxP of the establishment, including its refilling stations, shall be assessed and inspected by the FDA, for the purposes of the LTO application and PMS.

D. Compliance with Labeling Requirements Applicable for Cosmetics and HUHS Products for Refill

1. The cosmetic and HUHS refiller, including its refilling stations, shall ensure that the refilled product shall bear the mandatory labeling information for refilled cosmetic and HUHS products, following existing labeling requirements.
    a. The following minimum labeling information shall be printed, stickered, and/or stamped on the container for refill:
        i. Product Name
        ii. Batch or Lot Number
        iii. Net weight or volume
        iv. Directions for Use
        v. Storage Conditions
        vi. Date of Refill
        vii. Manufacturing/Expiry Date
        viii. Special Precautions (if any)
        ix. Statement that refilled product is not for resale
        x. Name and address of Market Authorization Holder (MAH)
        xi. Contact details of MAH for product complaints
    b. The refilled cosmetic and HUHS products shall not bear any product claims in the label that are not allowed and are beyond the scope of a cosmetic or HUHS product, respectively.
    c. Other labeling information required for cosmetic and HUHS products provided in the ASEAN Cosmetic Labeling Requirements and FC No. 2020-025, respectively, shall be made available to the consumer or buyer when requested.
    d. Other mandatory labeling information for HUHS products shall be covered by the transitory period provided in FC No. 2021-011-A, specifically on compliance with Annex J of FC No. 2020-025, including the GHS Label Elements, unless otherwise amended.

2. Bulk products shall bear the necessary product information and labeling to ensure product identity (i.e., product name, batch/lot number, volume/weight, manufacturing date, expiry date) and appropriate use (i.e., instructions/directions for use/refill, storage information, precautionary statements, warnings).

E. Responsibilities of the Cosmetic and HUHS Refiller Conducting the Refilling Activities

The Cosmetic and HUHS Refiller shall:

1. Ensure the safety, efficacy, quality, as well as traceability of the cosmetic and HUHS products for refill, including the monitoring and investigation of adverse events that may arise from using their product following the guidelines under FDA Circular No. 2016-012 "Guidelines on Product Recall" and its future amendments .

2. Refill only FDA-notified cosmetics and FDA-registered HUHS products.

3. Provide appropriate and up-to-date learning and development interventions to their personnel on the conduct of refilling activity, including training related to product quality and safety. Records of learning and development interventions shall be documented and kept on-site.

4. Ensure that only their employed trained personnel conducts the refilling activity. In-house training shall be acceptable, provided that the trainer is a Good Manufacturing Practices (GMP)-certified personnel of the Refiller who has received and has been certified in a GMP training by the FDA or by an FDA-recognized institution.

5. Ensure that the condition of the emptied product container shall be suitable, sanitized, and safe to use prior to refilling the product.

6. Ensure that suitable sampling and retention of samples shall be conducted on refilled products to allow testing for quality, safety, and efficacy.

7. Ensure that upon dispensing the refilled product, the consumer shall be reasonably informed of the refilled product, including but not limited to, safety information, frequency of reuse of the emptied product container, and proper disposal of emptied product container wastes.

8. Conduct information campaigns through Corporate Social Responsibility and Product Stewardship activities that aim to educate and improve consumer awareness regarding refilling activities and refilled products, including but not limited to, safety information, frequency of reuse of the emptied product container, and proper disposal of emptied product container wastes with compliance to Solid Waste Management Standards and Safe Practices consistent with Presidential Decree No. 856, also known as the "Sanitation Code of the Philippines", and RA No. 9003, also known as the "Ecological Solid Waste Management Act of 2000".

9. Coordinate with the FDA as a reportorial obligation on matters of PMS including but not limited to: (a) serious adverse events such as serious injury/illness resulting to hospitalization or death that can reasonably be attributed to the use of the cosmetic or HUHS product; (b) error in the manufacturing process of the cosmetic or HUHS product; and/or (c) availability of new scientific information that serves as evidence of the health hazard potential of the cosmetic or HUHS product; and shall refer to FDA Circular No. 2016-012 "Guidelines on Product Recall", its future amendments, and the additional reportorial mechanisms for adverse events in the use cosmetic products adopted through the ACD (*https://www.fda.gov.ph/wp-content/uploads/2021/03/Adverse-Event-Reporting-System.pdf*). Annex B of this issuance lists the Poison Control Centers in the Philippines.

10. Undertake the necessary measures immediately in case the cosmetic or HUHS product for refill has been withdrawn for health and safety reasons, such as inform the public on the risk of such product, shoulder incidental costs, ban its sale, distribution, or its immediate recall, withdrawal or seizure from the market, and its disposal in accordance with the rules and regulations issued by the Department of Environment and Natural Resources (DENR) in compliance with RA No. 9003, also known as the "Ecological Solid Waste Management Act of 2000," and RA 6969, also known as the "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990," and other standards, rules, and regulations adopted by the FDA.

11. Notify the FDA, through submission of a letter signed by the establishment owner/authorized representative/qualified personnel, to voluntarily cancel the applicable authorizations should the Refiller and/or its refilling stations cease to operate or engage in the previously-approved refilling activity.

F. Post-marketing Surveillance (PMS) of Cosmetic and HUHS Products for Refill and Imposition of Regulatory Actions Against Erring Establishments

1. The issuance of the LTO does not preclude FDA from conducting PMS activities in accordance with RA No. 3720 "An Act to Ensure the Safety and Purity of Foods, Drugs, And Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration Which Shall Administer and Enforce the Laws Pertaining Thereto", as amended by RA No. 9711.
2. Cosmetic and HUHS products for refill shall be subject to PMS activities of FDA. Applicable regulatory tools shall be undertaken or imposed upon erring establishments or products, whether refilled or still for refill, which are non-compliant with these guidelines and/or other applicable rules and standards.
3. The issued authorizations for the refilling activity and specific cosmetic and HUHS refilled products shall be subject to suspension, cancellation or revocation, or disapproval of the application for renewal, should any violation of existing FDA laws, rules, regulations and standards be committed by the erring establishment, including any of its refilling stations.

4. The FDA shall issue the necessary public health warnings and/or advisories for stakeholders and the public, pursuant to the PMS activities wherein violations to existing rules and regulations and/or risks to public health and safety are found.

G. Prohibited Acts

The following activities shall be prohibited:

1. The manufacture, importation, exportation, sale, offer to sale, transfer, promotion, advertising, or sponsorship of a cosmetic and/or HUHS product for refill without the appropriate authorization from the FDA.
2. The manufacture, importation, exportation, sale, offer to sale, transfer, promotion, advertising, or sponsorship of a substandard, adulterated, misbranded, and/or mislabeled cosmetic and/or HUHS product for refill.
3. The conduct of refilling activity by any other person other than the trained personnel required in this Order.
4. The conduct of refilling activity under circumstances which are not aligned with GxP.
5. The preparation of personalized or customized products in refilling stations; Wherein, personalized or customized products are defined as products: (1) that can be prepared on-site based on personal preferences of the consumer or, (2) which require further mixing, dilution, and/or other methods that will alter the formulation of the notified and/or registered product.
6. The on-site refilling of the primary container or dispenser of the finished bulk cosmetic and HUHS product in the refilling station.
7. The engagement of consumers to directly dispense the product on their own at the point of sale.
8. The resale of the refilled cosmetic and HUHS product.
9. The repacking of the refilled cosmetic and HUHS product.

VII. TRANSITORY PROVISIONS

A. Upon effectivity of this Order, the FDA shall issue implementing rules or guidelines for the provisions stated herein, including a pilot implementation of not more than six (6) months, preliminarily covering local Manufacturers engaged in refilling activities of Cosmetic and HUHS products.

B. Affected stakeholders shall be provided a transitory period of not more than six (6) months from the date of effectivity of the implementing rules or guidelines of this Order to allow covered establishments to comply with the new guidelines.

VIII. PENALTY CLAUSE

Violation of the prohibited acts under Item G of Section VI or any provisions of this Administrative Order shall be deemed as a violation of RA No. 3720, as amended by Executive Order No. 175 and further amended by RA No. 9711 because of either operating without proper authorization, or manufacturing or distributing substandard,

adulterated, misbranded, and/or mislabeled cosmetic or HUHS products, as the case may be. As such, it can be a ground for the disapproval of an application for LTO, or, after notice and hearing, be the bases for the suspension, cancellation or revocation of an issued LTO and/or imposition of other sanctions following the procedures under the Uniform Rules of Procedures of Book III of the Implementing Rules and Regulations of RA No. 9711.

IX. REPEALING CLAUSE

Relevant provisions under DOH Administrative Order 2020-0017, FDA Circular No. 2013-002, FDA Circular No. 2020-025, and other related issuances inconsistent or contrary to the provisions of this Administrative Order are hereby amended or modified accordingly.

X. SEPARABILITY CLAUSE

In the event that any part, section, or provision of this guideline is declared invalid or unconstitutional by a competent court of jurisdiction, the other provisions of this guideline, insofar as they are separable from the invalid ones, shall remain in full force and effect.

XI. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.

DR. TEODORO J. HERBOSA
Secretary of Health

ANNEX A
Related Issuances, Laws and Directives

1. Republic Act (RA) No. 3720 - An Act to Ensure the Safety and Purity of Foods, Drugs, And Cosmetics Being Made Available to the Public by Creating the Food and Drug Administration Which Shall Administer and Enforce the Laws Pertaining Thereto

2. RA No. 9711 - Food and Drug Administration (FDA) Act of 2009

3. Department Circular No. 2011-0101 - The Rules and Regulations Implementing Republic Act No. 9711 - The Food and Drug Administration Act of 2009

4. Department of Health (DOH) Administrative Order (AO) No. 2020-0017 - Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003

5. DOH AO No. 2005-0015 - Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents" adopting the ASEAN Cosmetic Directive

6. DOH AO No. 2019-0019 - Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products

7. FDA Circular No. 2020-025 - Implementing Guidelines for Administrative Order No. 2019-0019, "*Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products*"

ANNEX B
Poison Control Centers in the Philippines

Poison Control Center / Unit	Location	Contact Information
National		
National Poison Management and Control Center	Philippine General Hospital - College of Medicine, University of the Philippines. Taft Ave, Paco, Manila, 1000 Metro Manila	(02) 8524 1078 Globe: 09667189904 npmcc.uppgh@up.edu.ph
Regional		
Baguio General Hospital and Medical Center, Poison Control Unit	BGHMC Compound, Gov. Pack Rd, Baguio City, Benguet 2600	(074) 6617910 loc 396 Globe: 09958212771 bghmcpcu@gmail.com
Batangas Medical Center Poison Control Center	Bihi Road, Kumintang Ibaba, Batangas City 4200	(043) 7408307 loc 1104 Globe : 09177128745 Smart : 09218832633, 09199133102, 9189456879 toxfoura@yahoo.com
Bicol Medical Center Poison Control Unit	BMC Road, Concepcion Concepcion Pequeña, Naga City, Camarines Sur 4400	(054) 472 6125 to 31 Globe: 09165354692 Smart: 09480161575 bmcpcu@gmail.com bmc.nagacity@gmail.com
Corazon Locsin Montelibano Memorial Regional Hospital Biomarine and Toxicology Unit	Burgos-Lacson St., Bacolod City, Negros Occidential 6100	(034) 703 1350 Globe: 09178694510 clmmrh.toxicology@gmail.com clmmrh_coh@yahoo.com
East Avenue Medical Center Toxicology Referral and Training Center	East Avenue, Diliman, Quezon City, Metro Manila 1100	(02) 8921 1212 (02) 8928 0611 loc 707 Sun: 09232711183 eamctox@gmail.com
Eastern Visayas Regional Medical Center Poison Control Center	Tacloban City, Leyte 6500	(053) 8320308 Globe: 09773460358 Smart: 09283887722 evrmc.pcc@gmail.com

Jose B. Lingad Memorial General Hospital Poison Control Unit	Mac Arthur Highway, San Fernando City, Pampanga 2000	(045) 963 2279 (045) 961 2444 Sun: 09338746600, 09234117107 jblmrhtoxicology@gmail.com
Northern Mindanao Medical Center Poison Control Center	Capital Compound, Cagayan de Oro City 9000	(088) 7226263 (08822) 726362 Globe: 09058855645 Smart: 0968 202 6890 nmmctox@gmail.com
Rizal Medical Center Poison Control Unit	425 Pasig Blvd. Barangay Bagong Ilog, Pasig City 1600	(02) 8865 8400 loc 113 Globe: 09661783773 rizalmedpoisoncontrol@gmail.com pcu@rmc.doh.gov.ph
Southern Philippines Medical Center Poison Control and Treatment Institute	J.P. Laurel Ave, Bajada, Davao City 8000	(082) 227 2731 loc 5065 (082) 221 7029 Smart: 09992250208 spmcpoisoncontrol@gmail.com
Vicente Sotto Memorial Medical Center Poison Control Center	B. Rodriguez St., Sambag II, Cebu City 6000	(032) 253 9891 Sun: 09228496542 cebutoxcenter@gmail.com osm@vsmmc.doh.gov.ph
Western Visayas Sanitarium Poison Control Unit	Brgy. Inangayan, Santa Barbara, Iloilo 5002	(033) 523 8455 Smart: 09194980443 wvstoxunit@gmail.com
Zamboanga City Medical Center Poison Control Center	Dr. Evangelista St., Sta. Catalina, Zamboanga City, Zamboanga del Sur 7000	(062) 991 2934 (062) 992 0052 (062) 991 0573 Globe: 09155365583 zcmc.pcc@gmail.com