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REPUBLIC OF THE PHILIPPINES DEPARTMENT OF FINANCE BUREAU OF CUSTOMS

28 April 2015

NO. 45-2015

TO: All Deputy Commissioners All Directors and Chiefs All District / Port Collectors And All Others Concerned

SUBJECT: Registration Amnesty for Non-Compliant Do-It-Yourself and Hobby Items Classified as Household / Urban Hazardous Substance (HUHS) Products

Attached herewith is the letter of Dr. Janette P. Loreto-Garin, Secretary, Department of Health (DOH), dated 27 March 2015, informing the Bureau of the registration amnesty for do-it-yourself and hobby items, which are classified as household / urban hazardous substance products under Department Circular No. 2015-0098 of the DOH. This will, in effect, allow the movement of the specified goods by FDA-licensed establishments through the ports, including those products which are still to be registered or notified with the FDA.

For information and compliance.

Please confirm the dissemination of this circular throughout your offices within fifteen (15) days from receipt thereof.

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Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

23 March 2015

DEPARTMENT CIRCULAR No. 2015-0098

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TO

All Manufacturers, Traders and Distributors (Importers, Exporters, Wholesalers) of Do-It-Yourself Products and Hobby Items Classified as Household/Urban Hazardous Substances (HUHS) Products

SUBJECT

RE-ISSUANCE OF REGISTRATION AMNESTY FOR NON-COMPLIANT DO-IT-YOURSELF AND HOBBY ITEMS CLASSIFIED AS HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) PRODUCTS

In view of the school supplies stakeholders' request for extension of registration amnesty and finding such request reasonable, the same is hereby <u>extended until 31 December 2015</u> <u>only</u> to allow concerned school supplies manufacturers, traders and distributors (importers, exporters, wholesalers) to comply with the product notification requirements of the Food and Drug Administration (FDA) prior to the market of do-it-yourself and hobby items classified as household/urban hazardous substances (HUHS) products. The other requirements set in FDA Circular No. 2013-013 is, however, reiterated and shall be adhered to by the above-mentioned establishments.

On the other hand, during the period of registration amnesty set above, the FDA is directed to review all its regulation pertaining to do-it-yourself and hobby items classified as household/urban hazardous substances (HUHS) products and to submit its recommendation to the Office of the Secretary for consideration not later than 01 December 2015.

This Circular shall take effect immediately. For the guidance of all concerned.

JANETTE P. LORETO-GARIN, MD, MBA-H Secretary of Health

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 Direct Line: 711-9501 Fax: 743-1829; 743-1786 • URL: <u>http://www.doh.gov.ph;</u> e-mail: <u>osec@doh.gov.ph</u> ASTER COPY CMC 45-2015 PE



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



IV. Guidelines

- 1. A License to Operate (LTO) shall be secured from the Center for Cosmetic Regulation and Research (CCRR) before an applicant can file an application for market authorization.
- 2. The market authorization holder (MAH) is responsible for ensuring that the product in the market meets the FDA standards for safety and quality.
- 3. All establishments without valid FDA LTOs should secure a License to Operate compliant with the existing rules and regulations as prescribed in the FDA Circular 2013-009- Revised Guidelines on Licensing of HUHS.
- 4. An amnesty for a period of one (1) year shall be granted to all licensed establishments.
- 5. All licensed establishments should file an appropriate market authorization. During the amnesty period, the licensed establishments shall prepare all the necessary relevant documents in compliance with the registration requirements for HUHS products.
- 6. Within the amnesty period, there will be no sanctions or penalties that will be enforced against non-compliant establishments or their products; *Provided* that no unresolved safety and quality issues or concerns regarding the product exist.
- 7. All applications filed before the approval of this Circular shall be processed accordingly by the CCRR.
- 8. The CCRR reserves the right to ask for additional requirements to verify or validated claims and to determine the safety and quality of the product. Additional label may be required to ensure the safe use of the product, among others
- 9. All applicants shall be requested to submit all application requirements to the CCRR or other FDA offices. When an on-line application is available at fda.gov.ph, the applicant has the option to file their application electronically.
- 10. The LTO and Certificate of Product Listing shall be issued by the FDA only when the requirements have been complied and the standards are met.

V. REQUIREMENTS

- A. License to Operate
 - 1. The following is the set of requirements for application of license as HHS establishment as trader, distributor or manufacturer:

Civic Drive, Filinvest Corporate City, Alabang, City of Muntinlupa 1781 Philippines 857-1900 or 165-332 (trunkline) 8070751 (fax) <u>info@fda.gov.ph</u> (email) <u>www.fda.gov.ph/</u> beta.fda.gov.ph