Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 May 2013

FDA CIRCULAR
No. 2013-013
CENTER FOR COSMETICS REGULATION AND RESEARCH

Subject: Registration Amnesty for Non-Compliant Products Specifically Under Product Classification, Category IV- Do-It-Yourself and Hobby Products, Classified as Household/Urban Hazardous Substances (HUHS)

I. Background/Rationale

Administrative Order No. 312, series of 1977, Presidential Decree No. 881, and Republic Act No. 9711, otherwise known as the FDA Act of 2009, recognize that some household items or products may have health effects and may contain hazardous substances or may be sources of exposure from hazardous substances. These household items or products differ in risk, which is a function of hazard and exposure, compared with other household hazardous substances categorized by the FDA.

Do-it-yourself and hobby items, such as glues and cement, dyes, ink and ink cartridges, gem bluer, educational sets e.g. crayons, pencils, pens and miscellaneous chemistry sets and other similar products, are considered household/urban hazardous substances as stipulated by R.A. No. 9711. These products may have effects on health which require regulations of the FDA. These products, compared with other categories of household hazardous substances stipulated in Administrative Order No. 312, series of 1977, under the authority of Presidential Decree No. 881, namely 1) products containing petroleum distillates, 2) polishes and waxes, 3) cleansers and detergents, 4) yard and home products, such as air freshener and insecticides, are relatively less hazardous and when used as indicated present practically no risk.

II. Objectives

The objective of this Circular is to set the guidelines for the registration amnesty of covered products as identified under Scope and Coverage. This is to encourage registration of products that presently do not have authorization from FDA.

III. Scope and Coverage

This Circular shall cover household/urban hazardous substances that are do-it-yourself and hobby items and products, such as glues and cement, dyes, ink and ink cartridges, crayons, pencils, ballpoint pens, fountain pen, gem bluer, educational sets and miscellaneous chemistry sets, and among other similar low risk products.

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:

a. Notarized Letter of Application
b. Copy of DTI Certificate of Registration for single proprietorship or SEC for corporation or partnership
c. Copy of contract of agreement with trader or distributor, when applicable
d. Vicinity Map/Google Map of the establishment

2. The FDA shall inspect the establishment for verification or validity of the requirements submitted and the information given. A Certificate of Compliance shall be issued by the FDA Inspectorate after inspection.

B. Market Authorization

1. The following is the set of requirements for application of market authorization of the less toxic products classified as HHS:

a. FDA LTO
b. Application for Product Listing*
c. Risk Management Plan
d. Complete List of Ingredients (Formulation)
e. Certificate of Analysis of Finished Product
f. Sample of the Product or Photo of the Product and Scanned Facsimile Label including the Use of the Product and Direction for Use, when applicable

*Forms will be provided by the Center for Cosmetics Regulation and Research

2. The FDA inspector shall inspect the actual product in the establishment or market. When applicable, the FDA inspector shall ensure that the applicant has Safety Data Sheet(s) (SDS) on file. The SDS file shall remain in the possession of the applicant and shall be made available to FDA in case there are safety issues regarding the product. When requested by the CCRR, the license-holder shall send the SDS electronically through fax or email.

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

KENNETH Y. HARTIGAN-GO, MD
Acting Director IV