Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 0 8 2015

ADMINISTRATIVE ORDER
No. 2015 - ~~(s. 2015)~~ 0038

SUBJECT : **REMOVING THE 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**

I. BACKGROUND AND RATIONALE

Administrative Order No. 312 (s. 1977) declared certain items as hazardous pursuant to Section 2, par. 1 of Presidential Decree No. (PD) 881 (s. 1976), in relation to Section 2, par. 2 thereof, and in light of existing pieces of evidence then. FDA Memorandum Circular No. 2013-045 (s. 2013) added certain items on the list of hazardous substances.

In view of the minimal risk and hazard posed to the health and safety of the people and based on standards being practiced and followed by foreign regulatory institutions on household hazardous items falling within the jurisdiction of their local FDA, the requirements of license to operate and product registration or notification shall not be imposed on the importation, exportation, manufacture, sale, distribution, retail and related activities on certain household/urban hazardous substances. However, importers, exporters, manufacturers, toll manufacturers, wholesalers, distributors, retailers, or re-packers are not exempted from certain regulatory actions of the FDA, particularly on post-marketing surveillance, monitoring and compliance.

II. OBJECTIVES

To remove the requirements of licensing as importers, exporters, manufacturers, toll manufacturers, wholesalers, distributors, retailers, or re-packers of those engage in certain household/urban hazardous substances, and from the requirement of prior registration and/or notification of said products, to facilitate the process considering that said items pose minimal risk and hazard to the health and safety of the people, as well as to enable the FDA to focus its time and resources in regulating food, drugs and goods that have higher impact on the health and well-being of the Filipinos.

III. SCOPE AND APPLICATION

This Administrative Order applies to the public in general and to the entities and products regulated by the Food and Drug Adminsitration based on previous issuances from the Secretary of Health, the Director General of the Food and Drug Administration, or its Center for Cosmetic Regulation and Research, the Center tasked to regulate household hazardous substances.

IV. GENERAL PROVISIONS

The requirement of licensing as importers, exporters, manufacturers, toll manufacturers, wholesalers, distributors, retailers, or re-packers of those engage in certain household/urban hazardous substances, and from the requirement of prior registration and/or notification **shall <u>not</u> be required of the following products prior to their importation, exportation, manufacture, sale, distribution, retail, promotion, and offer for sale**:

1. Educational set and miscellaneous chemistry set;
2. Stationeries/art paper (colored and or scented);
3. Polishes and Waxes (metal polish, wood polish, shoe polish);
4. Bleaches;
5. Cleaners;
6. Disinfectant sprays;
7. Detergents (bar, liquid and powder)
8. Dishwashing (liquid and paste);
9. Glues/Paste;
10. Fabric (dyes, softeners, conditioners);
11. Adhesives;
12. Room freshener/air fresheners and deodorizer;
13. Paints, lacquers, varnish; and
14. Solvent paint, lacquer thinner, mineral spirits.

V. SPECIFIC PROVISIONS

The manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of such substances, **shall <u>not</u> anymore require prior FDA approval and clearances**. Manufacturers, importers, exporters, wholesalers, distributors, retailers, and the like **shall <u>not</u> anymore be required to secure License to Operate, or undergo product registration and/or notification by the FDA before they can engage in the aforementioned activities**.

However, manufacturers, importers, exporters, wholesalers, distributors, retailers, and the like shall strictly comply with the standards set by pertinent laws or rules and regulations on said household/urban hazardous substances. The FDA shall vigorously conduct post-marketing surveillance on all importers, exporters, manufacturers, toll manufacturers, wholesalers, distributors, retailers, re-packers and the like who are engaged on these products and strictly enforce the pertinent standards and penalties.

Further, pursuant to Republic Act No. (RA) 3720, as amended by RA 9711, and its IRR, the Director-General has the right to:

(a) Issue cease and desist orders *motu proprio* or upon verified complaint against health products not compliant with pertinent standards, whether or not said health are registered with FDA;

(b) After due process, order the ban, recall, and/or withdrawal of any of the aforementioned health products found to have caused the death, serious illness, or serious injury to a consumer or patient, or is found to be immediately injurious, unsafe, dangerous, or grossly deceptive;

(c) Issue orders of seizure, or to seize and hold in custody any of the aforesaid health products/substances that are adulterated, counterfeited or misbranded;

(d) Impose administrative sanctions on the erring persons or entities; and

(e) Take other legal measures to protect the health and safety of the public pursuant to RA 9711.

The, FDA, with the approval of the Secretary of Health, may require prior FDA registration and/or approval before engaging in their manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of such substances, at any time when threat to public health and safety is imminent.

VI. REPEALING CLAUSE

This Order effectively amends AO No. 312 (s. 1977) and FDA Memorandum Circular No. 2013-045 (s. 2013). The provisions of previous Orders and other related issuances inconsistent with or contrary to the provisions of this Administrative Order are hereby revised, modified, repealed or rescinded accordingly. All provisions of existing issuances which are not affected by this Order shall remain valid and effective.

VII. IMPLEMENTATION

When necessary, the FDA may issue rules or guidelines consistent with this Order to further clarify the provisions of this Order and to facilitate its implementation.

A copy of this A.O. shall be furnished to the Bureau of Customs to ensure that exporters and importers of the items specified in this A.O. shall not be required anymore of License to Operate and/or product registration/notification.

VIII. EFFECTIVITY

This order shall take effect immediately.

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