

December 9, 2015

CUSTOMS MEMORANDUM CIRCULAR NO. 175 - 2015

To:

All Deputy Commissioners

All Directors

All District and Subport Collectors

And Others Concerned

SUBJECT: SELECTED HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS)
PRODUCTS COVERED BY DOH ADMINISTRATIVE ORDER NO. 20150038

Attached is the letter dated October 23, 2015 of Secretary Janette P. Loreto-Garin, Department of Health endorsing a copy of A.O. 2015-0038 entitled: "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."

It is informed that item VII thereof states:

"VII. IMPLEMENTATION

XXX

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."

For your information and guidance.

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

ALBERTO D. LINA

Commissioner

Bureau of Customs ~
ALBERTO D. LIN A
Commissioner
15-02989



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



23 October 2015

HON. ALBERTO D. LINA
Commissioner
BUREAU OF CUSTOMS
Office of the Commissioner
G/F OCOM Bldg., Port Area, Manila



Subject: Selected Household/Urban Hazardous Substances (HUHS)
Products Covered by Administrative Order No. 2015-0038

Dear **COMMISSIONER LINA**:

Greetings!

This refers to your letter dated 21 October 2015 requesting for clarification if inks are included in the list of household/urban hazardous substances (HUHS) covered by Memorandum Circular No. 2015-024 "List of Household/Urban Hazardous Substances (HUHS)".

Primarily, please note that the Department of Health (DOH) has issued <u>Administrative Order No. 2015-0038</u> which provided for the removal of requirements of licensing as importers, exporters, manufacturers, toll manufacturers, wholesalers, distributors, retailers, or re-packers of those engaged in certain HUHS products, and from the requirement of prior registration and/or notification of said products. This Order took effect on 08 September 2015.

Memorandum Circular No. 2015-024 "List of Household/Urban Hazardous Substances (HUHS)", as cited in your letter, was issued by the Philippine Economic Zone Authority (PEZA) informing the economic zone enterprises, administrators and managers on the content of A.O. 2015-0038.

With reference to the letter received by your Office on 01 October 2015, this is to confirm that with the issuance of A.O. 2015-0038, the manufacture, importation, exportation, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of (certain) household/urban hazardous substances (HUHS) specified under Sec. IV shall <u>not</u> anymore require prior FDA approval and clearances. Further, 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.





Specifically, this Order covers products that are categorized as Household/Urban Hazardous Substances as per BOC's list of regulated imports as of 06 April 2015 (http://customs.gov.ph/regulated-imports-list-2015-04-06/) for which inks are included.

To reiterate, FDA shall no longer issue BOC Clearances to establishments that import such HUHS products effective immediately. Likewise, BOC is hereby advised to no longer require importers to present License to Operate (LTO), Certificate of Product Registration (CPR) or Product Notification (HH) and/ or BOC Clearances prior to release of the aforementioned HUHS products from the port.

Attached are copies of Administrative Order No. 2015-0038 and PEZA Memorandum Circular No. 2015-024 for your reference and perusal.

The BOC is also requested to post copy of A.O. 2015-0038 in its website for the guidance of exporting countries to the Philippines and to update its list of regulated imports accordingly.

For your guidance and strict compliance.

Very truly yours,

JANETTE P. LORETO-GARIN, MD, MBA-H

Secretary of Health Acting Director General¹

cc: AGATON TEODORO O. UVERO

Deputy Commissioner
BUREAU OF CUSTOMS
Assessment and Operations Coordinating Group
G/F CRIC Bldg., BOC, Port Area, Manila

ARIEL F. NEPOMUCENO
Deputy Commissioner
BUREAU OF CUSTOMS
Enforcement Group
G/F CRIC Bldg., BOC, Port Area, Manila

¹Pursuant to DPO 2015-1845 DTN: 20151022170156

Attachment: A.O. 2015-0038, PEZA M.C. 2015-024 BCS/MBK/mdl



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, toli 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.

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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.

VIIL EFFECTIVITY

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Philippine Economic Zone Authority

MEMORANDUM CIRCULAR NO. 2015 - 024

FOR

: Economic Zone Locator Enterprises

Economic Zone Administrators and Magagers

FROM

Director General LILIA B. DE LIMA

SUBJECT

Chemical Importation Advisory - Removing FDA

requirements for the importation of goods considered as

household urban hazardous substance (HUHS)

DATE

24 September 2015

We wish to inform that the Department of Health (DOH) has issued Administrative Order 2015-0038, also known as "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 (HUHS) and from the requirement of prior registration and/or notification of said products" dated 08 September 2015. Attached herewith as **Annex A**, is a copy of DOH AO 2015-0038.

Thus, effective immediately, no FDA permits or clearances are required for the importation of items considered as HUHS which are as follows:

- A. Paints (household/car paints), lacquers, varnish;
- B. Paint solvent, lacquer thinner, mineral spirits, turpentine;
- C. Adhesives and sealants:
- D. Polishes and waxes;
- E. Bleaches:
- F. Cleaning agents;
- G. Disinfectants;
- H. Detergents:
- I. Dishwashing liquid and pastes;
- J. Dyes, softeners, conditioners, fresheners, ironing agents for fabrics;
- K. Educational set and miscellaneous chemistry set (paste, pencils, pens and markers, water colors, glues, fluid/rubber erasers, crayons, oil pastels, chalk, moulding clays, inks);
- L. Paper (colored and/or scented);
- M. Air fresheners (deodorizer, scented candles, gels, oil spray, dehumidifier);
- N. Lubricants, brake fluid and rust inhibitors.

[Reference: Section II. Scope and Coverage FDA MC 2013-045]

This advisory repeals PEZA Memorandum Circular 2015-008 which requires importers to secure clearance from the FDA to ensure release of shipment.

You may visit the PEZA Zone Office or email esg@peza.gov.ph for assistance or additional concern.

For information.



1519-2015-00253



