2015_07-017

MASTER COPY

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS

OFFICE OF THE COMMISSIONER

MEMORANDUM

TO	:	**ALL DEPUTY COMMISSIONERS** **ALL DISTRICT/SUB-PORT COLLECTORS** **ALL CHIEFS, FORMAL ENTRY DIVISION** **ALL OTHER CONCERNED**
FROM	:	**ALBERTO D. LINA**
SUBJECT	:	**Implementation of FDA Memorandum Circular No. 2015-006 and a reminder of FDA Circular 2013-015**
DATE	:	**14 July 2015**

In view of the attached letter from Maria Theresa M. Gutierrez, Rph, MSc, OIC-Director, Center for Cosmetics Regulation and Research, Food and Drug Administration dated 01 July 2015, inviting attention to the information on the immediate implementation of FDA Memorandum Circular No. 2015-006; it is also informed that all importers of raw materials for cosmetic and HUHS are no longer under the jurisdiction of FDA-CCRR due to FDA Circular 2013-015 and all concerned are reminded that CCRR will no longer be requiring License to Operate (LTO) and Certificate of Product Registration (CPR)/acknowledge notification for those companies that are importing HUHS in finished form intended solely for their own consumption and not to be marketed commercially or for wholesale distribution but shall issue BOC Clearance per shipment.

The Officer-in-Charge, Internal Administration Group is instructed to send this Memorandum to the Chiefs, Central Record Management Division (CRMD) for the drafting of Customs Memorandum Circular and the Public Information and Assistance Division (PIAD), for updating of our website for the information of our stakeholders and the general public as well.

For your information and reference.

Please be guided accordingly.

ALBERTO D. LINA
Commissioner

Bureau of Customs
ALBERTO D. LINA
Commissioner
15-00862

JUL 15 2015

Encl.:a/s
15-07709
Fda/07.13.2015

South Harbor, Gate 3, Port Area, Manila 1099 • Tel. Nos. 705-6052, 705-6067 (CRMS)
Website: www.customs.gov.ph • Email: helpdesk2@customs.gov.ph (CRMS)

2015_077 - 017 Pg 3

MASTER COPY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA
Food and Drug Administration
PHILIPPINES

05 June 2015

FDA MEMORANDUM CIRCULAR
No. 2015-006

SUBJECT : **RELEASE OF IMPORTED HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) FINISHED PRODUCTS FROM THE BUREAU OF CUSTOMS (BOC) INTENDED SOLELY FOR OWN CONSUMPTION**

After a number of inquiries from and consultations with stakeholders engaged in the importation of household/urban hazardous substances (HUHS) in finished form and are intended solely for their own consumption, the Center for Cosmetics Regulation and Research (CCRR) recognizes that these finished products shall not be for marketing nor shall be for commercial or wholesale distribution.

In consideration thereof, CCRR shall issue Bureau of Customs (BOC) Clearance per shipment in lieu of the License to Operate (LTO) and product registration/notification (CPR/NN) subject to the following requirements:

1. Letter of Intent
2. Notarized Affidavit of Undertaking stating that the imported product does not contain any banned ingredient/s and is intended solely for own consumption and shall not be for marketing nor shall be for commercial or wholesale distribution
3. Copy of shipping documents (such as Bill of Lading, Invoice and Packing List)
4. Proof of Payment (Php 510.00/shipment).

Likewise, for clarification, it is hereby reiterated that raw materials used in the manufacture of cosmetics and/or household/urban hazardous substances (HUHS) are no longer being regulated by FDA-CCRR pursuant to FDA Circular No. 2013-015 "Deregulation of Bulk Industrial Chemicals Used as Raw Materials In Cosmetic Products and Household Products Considered as Urban Hazardous Substances" and that the release of said raw materials from the BOC shall no longer require LTO and CPR/NN pursuant to FDA Memorandum Circular No. 2013-032 "Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs".

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

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTL: 20150605165701
[1]Pursuant to DPO 2015-1845

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

2015 – 07 – 017 Pg. 5

MASTER COPY

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Penalties for Certain Violations Thereof and for Relevant Purposes, RA No. 8294, otherwise known as An Act Amending the Provisions of Presidential Decree No. 1866 and PNP SOP NP No. 4; the Philippine Drug Enforcement Agency (PDEA) by virtue of RA 9165 of 2002, An Act Instituting the Comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the Dangerous Drugs Act of 1972, as amended, providing funds therefore, and for other purposes and Board Regulation No. 3-2003, Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other lawful Acts in Connection With Any Dangerous Drugs, Controlled Precursors and Essential Chemicals and Other Similar or Analogous Substances.

In view of the above, all industrial chemicals, whether local or imprted, in raw and in bulk forms, for industrial use and intended for further processing as ingredients to manufacture or produce cosmetic products or preparation of HUHS falling within the definition of HUHS except for Household/Urban Pesticides shall no longer be regulated by this Office.

All establishments with existing FDA License to Operate (LTO) as Raw Material Manufacturer, Trader or Distributor, or both, for Cosmetics and HUHS and all market authorization holders of valid Certificate of Product Registrations (CPR), are hereby advised not to renew the said FDA authorizations. However, any establishments packaging and labeling industrial chemical into consumer products must secure proper authorization from the FDA.

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

KENNETH Y. HARTIGAN-GO, MD
Acting Director General