REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS

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20 July 2015

CUSTOMS MEMORANDUM CIRCULAR
NO. 94-2015

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

SUBJECT: **FDA Memorandum Circular No. 2015-006 - "Release of Imported Household / Urban Hazardous Substances (HUHS) Finished Products from the Bureau of Customs (BOC) Intended Solely for Their Own Consumption" and; FDA Memorandum Circular No. 2013-015 – "Deregulation of Bulk Industrial chemicals Used as Raw Materials in Cosmetics and Household Products Considered as Urban Hazardous Substances"**

Attached herewith is the letter of Ms. Maria Theresa M. Gutierrez, RPh, MSc, Officer-in-Charge, Center for Cosmetics Regulation and Research (CCRR), informing the Bureau of the immediate implementation of the Food and Drug Administration (FDA) Memorandum Circular No. 2015-006, wherein the CCRR will no longer be requiring License to Operate and Certificate of Product Registration (CPR) or acknowledge notifications 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.

And also, pursuant to FDA Memorandum Circular No. 2013-015, all importers of raw materials for cosmetics and HUHS is no longer under the jurisdiction of FDA CCRR.

For information and compliance.

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

ALBERTO D. LINA
Commissioner

Bureau of Customs
ALBERTO D. LINA
Commissioner
15-00903

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FOOD AND DRUG ADMINISTRATION

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FDA
Food and Drug Administration
PHILIPPINES

01 July 2015

BUREAU OF CUSTOMS
ASSESSMENT AND OPERATIONS COORDINATING GROUP

RECEIVED BY: MACHELLE
DATE/TIME: 07-07-2015 10:00 am
2015-07-1395

HON. ALBERTO D. LINA
Commissioner,
Bureau of Customs (BOC)
G/F OCOM Building, South Harbor,
Gate 3, Port Area, Manila

Attention: **ATTY. AGATON TEODORO O. UVERO**
Deputy Commissioner,
Assessment and Operations Coordinating Group, BOC

Dear **Commissioner Lina:**

Greetings!

The Center for Cosmetic Regulation and Research (CCRR), Food and Drug Administration (FDA) shall be implementing immediately ***FDA Memorandum Circular No. 2015-006 "Release of Imported Household/ Urban Hazardous Substances (HUHS) Finished Products from the Bureau of Customs (BOC) Intended Solely for Their Own Consumption"***.

CCRR will no longer be requiring License to Operate (LTO) and Certificate of Product Registration (CPR)/ acknowledged notifications 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.

Likewise, we would like to remind your Office that all importers of raw materials for cosmetic and HUHS is no longer under the jurisdiction of FDA – CCRR because of ***FDA Circular 2013-015 "Deregulation of Bulk Industrial Chemicals Used as Raw Materials in Cosmetics and Household Products Considered as Urban Hazardous Substances"***.

Attached herewith are the aforementioned documents for information and guidance, thank you very much.

Very truly yours,

MARIA THERESA M. GUTIERREZ, RPh, MSc
OIC-Director, Center for Cosmetics Regulation and Research

Cc: **MS. NEMIA T. GETES,** *Officer-In-Charge*, FDA Customs Liaison Unit

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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

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 June 2013

FDA Circular
No. 2013-015
Center for Cosmetic Regulation and Research

SUBJECT: DEREGULATION OF BULK INDUSTRIAL CHEMICALS USED AS RAW MATERIALS IN COSMETIC PRODUCTS AND HOUSEHOLD PRODUCTS CONSIDERED AS URBAN HAZARDOUS SUBSTANCES

A cosmetic product is intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly of cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting them, and Household/Urban Hazardous Substance (HHUS) product falling under the definition of household/urban hazardous substances is any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizers, agricultural pesticides, and agricultural insecticides, and other economic poisons, radioactive substances, or substances intended for use as fuels, coolants, refrigerants and the like. require FDA approval and market authorization by virtue of Republic Act (RA) No. 9711 or the FDA Act of 2009.

Several government agencies are mandated by law to regulate the manufacture. importation, export, distribution, storage, transport, sale and use of industrial chemicals and hazardous waste materials, namely DENR Environmental Management Bureau by virtue of RA No. 6969 of 1990, An Act To Control Toxic Substance and Hazardous and Nuclear Wastes, Providing Penalties For Violations Thereof, and for Other Purposes; Department of Labor and Employment (DOLE) by virtue of Presidential Decree No. 442, Book 4, Title I, Chapter II; the Philippine National Police (PNP) Fire and Explosives Division by virtue of Executive Order No. 522, Presidential Decree No. 1866 on Codifying the Laws on Illegal/Unlawful Possession, Manufacture, Dealing in, Acquisition or Disposition, of Firearms, Ammunition or Explosives or Instruments Used in the Manufacture of Firearms, Ammunition or Explosives, and Imposing Stiffer

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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