REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS
MANILA 1099

April 11, 2014

CUSTOMS MEMORANDUM CIRCULAR NO. 54- 2014

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

SUBJECT: Matrix of Appropriate Requirements on the Release of Products under FDA Jurisdiction

Attached is the letter dated March 25, 2014 of Ms. Nemia T. Getes, OIC, Customs Liaison Unit, Food and Drug Administration (FDA), duly noted by FDA Director General Kenneth Y. Hartigan-Go, providing this Bureau with a Matrix of appropriate requirements on the release (import/export) of products under FDA jurisdiction.

For further clarification, you may contact the FDA thru telephone nos. 857-1900 local 2141 or 857-1977.

For your information and guidance.

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

JOHN P. SEVILLA
Commissioner

Bureau of Customs
JOHN P. SEVILLA
Commissioner
14-01362
APR 16 2014

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA

Internal Admin. Group
Received by: VICKY REYES
Date: 04/01/14
Time: 11

25 March 2014

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HON. JOHN PHILIP J. SEVILLA
Commissioner
Bureau of Customs
OCOM Bldg., Port of Manila

Attention : **JESSIE DELLOSA**
Deputy Commissioner

Dear Commissioner Sevilla:

Greetings!

We are providing you herewith a Matrix of appropriate requirements for your easy reference on the release of products under FDA jurisdiction.

For further clarification, please do not hesitate to contact us at telephone nos. 8571900 Local 2141 or 8571977.

Thank you for usual support on matters of mutual concern..

Very truly yours,

NEMIA T. GETES
FDRO V
OIC, Customs Liaison Unit
FDA Operations Cluster

Noted by:

KENNETH Y. HARTIGAN-GO, MD
Acting Director General

TABLE I. Importation

PRODUCT CATEGORY	PRODUCT DESCRIPTION/ FORM	REQUIREMENTS PRIOR TO BOC RELEASE	
		1. Valid License To Operate (LTO)	2. Valid Certificate of Product Registration (CPR) or Notification No. (NN)
		Note : In case where LTO, CPR, and/or NN are ongoing renewal, please accept any of the following: a. Document Tracking Number within (3) months from date of application b. CTC of Assessment Slip or Copy of application received by FDA	
DRUGS	Finished Product	valid LTO as Drug Importer	valid CPR
	Finished product in bulk	valid LTO as Drug Manufacturer or valid LTO as Drug Trader	valid CPR
	Raw materials for local sale/ distribution	valid LTO as Drug Importer	Not Applicable (N/A)
	Raw materials for own use	valid LTO as Drug Manufacturer or valid LTO as Drug Trader	N/A
PROCESSED FOOD / FOOD PRODUCTS	Finished Product	valid LTO as Food Importer	valid CPR
	Finished product in bulk as:		
	a.Raw materials, food ingredients, food additives for own use	valid LTO as Food Manufacturer	N/A
	b.Raw materials, food ingredients, food additives for local sale/ distribution	valid LTO as Food Importer	N/A Note: valid CPR shall be required by 01 Sept. 2014
	c. for packing into its final product presentation for retail	valid LTO as Food Importer/Wholesaler	valid CPR
Foods covered under Food Fortification Law	Wheat Flour, Cooking Oil, Refined Sugar	valid LTO as Food Importer	valid CPR, *CoA (batch specific per shipment)
	Iodized Salt	valid LTO as Food Importer	valid CPR

COSMETICS	Finished Product	valid LTO as Cosmetic Importer	Notification
	Raw materials for own use or local sale/distribution	N/A	N/A
HOUSEHOLD/ URBAN HAZARDOUS SUBSTANCES (HUHS)	Finished Products	valid LTO as H/UHS Importer	valid CPR or Notification
	Raw materials for own use or local sale/distribution	N/A	N/A
PESTICIDES	Finished Product	valid LTO as HUHS Importer	valid CPR
	Raw Materials	valid LTO as HUHS Manufacturer or as H/UHS Importer	valid CPR
TOYS (For ages 14 years and below only) *Toys for ages 14 years and above are exempted from LTO*	Finished Products	valid LTO as H/UHS Importer	FDA Conditional Release
MEDICAL DEVICES	Registrable Medical Devices (invasive, in- vitro)	valid LTO as Medical Device Importer	valid CPR
	Non-registrable medical devices	FDA Certificate of Exemption for LTO	FDA Certificate of Product Exemption (COE)
RADIATION DEVICES	Radiation device	N/A	For Customs Release
	Non-radiation device	N/A	FDA Certification of non-radiation emitting equipment
HEALTH-RELATED DEVICE	Ex. water filtration, purification device; hospital waste disinfection device	N/A	valid CPR

Table II. For Exports

The following are requirements for exportation of :

Processed Food/ Food Products	valid LTO, valid CPR, and Commodity Clearance
Drug, Cosmetics, Devices	valid LTO, valid CPR or Notification (for cosmetics)

Table III. Others

Importation intended as follows:

PURPOSE OF IMPORTATION	**REQUIREMENTS PRIOR TO BOC RELEASE**	**REMARKS**
Donation: Drugs	FDA Certification/Permit	Subject to FDA inspection and collection of representative samples
Donation: Medical Devices	FDA Certification /Permit	
Donation: Processed Food	FDA Certification/Permit	Importer shall submit to FDA representative sample
Research	FDA Certification/Permit	
Clinical Trials	FDA Certification/Permit	
Exhibits/Trade Promotion	FDA Certification/Permit	
Samples for product registration	FDA Certification/Permit	
Compassionate Use	FDA Certification/Permit	
Personal Use	FDA Certification/Permit	

*CoA- Certificate of Analysis

Prepared by :

NEMIA T. GETES, RPh, MM
FDRO V
OIC, Customs Liaison Unit
FDA Operations Cluster

Noted by:

KENNETH Y. HARTIGAN-GO, MD
Acting Director- General