Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

10 September 2013

FDA Memorandum Circular
No. 2013-035

TO : **All Food Importers/Distributors, FDA Personnel, The Bureau of Customs, and Other Concerned Parties**

SUBJECT : **SIX (6) MONTHS MORATORIUM ON THE REQUIREMENT OF CERTIFICATE OF PRODUCT REGISTRATION FOR RAW MATERIALS TO BE PRESENTED OR SUBMITTED TO THE BUREAU OF CUSTOMS PRIOR TO RELEASE, AS PER FDA MEMORANDUM CIRCULAR 2013-032, DATED 28 AUGUST 2013**

The Food and Drug Administration (FDA) Circular 2013-032 dated August 28, 2013 states that "a.ii. Food ingredients and food additives, among other raw materials, that are intended for distribution or for sale, the License to Operate (LTO) and the Certificate of Product Registration (CPR) shall be presented or submitted to the Bureau of Customs" for the immediate release of the products in the market to make them available and accessible to the public.

However, the implementation of Memorandum Circular (MC) 2013-032 has revealed and disclosed quite a number of FDA-licensed food importers/distributors of raw materials that failed to secure the CPR as required by R. A. No. 9711, otherwise known as the FDA Act of 2009. The Implementing Rules and Regulations (IRR) of RA 9711 was signed only in 2011. Prior to the signing of the FDA Act of 2009 and its IRR, R.A. No. 3720, series of 1963, otherwise known as the Food, Drugs and Devices, and Cosmetic Act, as amended by E. O. No. 175 in 1987, has no specific provision on registration of raw materials.

This FDA Memorandum Circular is being issued to ensure continuous supply of processed food products that are manufactured in the country for domestic use and export to international market.

In the interest of public service, it is hereby ordered that all FDA-licensed food importers and distributors of raw materials that are intended for distribution and sale to consumers and other food establishments shall secure a CPR for every raw material within six (6) months. A six-month moratorium shall be imposed on the provision of the FDA Circular 2013-032 that requires all raw materials that are intended for distribution and sale to have CPR prior to release by the Bureau of Customs. Only an LTO shall be presented or submitted to the Bureau of Customs

until February 28, 2014, after which the LTO and the CPR shall be required starting on March 1, 2014.

The following are the Center for Food Regulation and Research (CFRR) requirements for securing a CPR of raw materials:

1. Letter of Application addressed to the Director of the CFRR,
2. Valid FDA LTO as food importer/distributor, and
3. Notarized Affidavit of Undertaking.

For more details and inquiries, you may email info@fda.gov.ph, with a subject heading of "CFRR".

This Memorandum Circular shall take effect immediately.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General

TEMPLATE
Application Form for Product Registration of Raw Materials/ Ingredients/ Food Additives

[[COMPANY LETTERHEAD]]

The Director
Center for Food Regulation and Research
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Sir/Madam:

In accordance with R.A. 9711 and other related issuances, we (company name) _____, having LTO number ___ issued on ___ valid until ____, wish to apply for the registration of the following raw material/s, ingredients and food additives:

PRODUCT/S*	TYPE OF REGISTRATION*		
	INITIAL	RE-APPLICATION	RENEWAL

*Check the type or registration if applied

Along with this application is the Affidavit of Undertaking, copy of our valid LTO.

We categorically declare that all data and information submitted in connection with this application as well as other submission in the future are true and correct.

We further bind ourselves to all safety and quality issues that may arise from these products.

Date: _____

Company Name:
_____

By:
_____
Indicate Authority
(e.g whether owner / proprietor / partner or duly authorized representative of the company)

AFFIDAVIT OF UNDERTAKING

_____of legal age, _____
(name of applicant) (position in the company)
and/or duly authorized representative or _____
(name of company and address)
_____, after having sworn in accordance with law, hereby declare that:

1. The aforementioned company will import/ manufacture the raw material/ ingredient/ food additives to be supplied, distributed and offered for sale to food establishments, food manufacturers, food processors or customers with the following details on Product Information:

Product Information

Brand Name – if applicable

_____

Product Name

_____

Complete Company Name and address – as listed in the LTO

_____

Contact Number(s)

_____

E-mail address:

_____

Country of origin (if imported)

_____

Complete Name and Address of the Supplier (if not directly sourced from the manufacturer)

_____

Complete Name and Address of Manufacturer (if imported)

_____

Ingredients list:(list all specific name of the ingredients in descending order) – if applicable

1.

2.

3.

4.

PRODUCT SPECIFICATIONS:

Physical description:

_____

_____

_____

_____

Chemical and/or Microbiological specifications:

_____

_____

_____

_____

Shelf life declaration (indicate if actual or accelerated)

_____

Packaging material type/ name and Description of Product as Packed (please attach label)

_____

Storage condition requirement:

_____

Food application (e.g preservative, nutrient, emulsifier, bakery ingredient) – function of the food material

_____

Usage: (especially for food additives with limits) – if applicable

_____

Source of allergen / ingredient allergen (if any):

_____

Lot Code and Interpretation:

_____

Open Date Marking (e.g. Date of Manufacture, Expiration Date) – if applicable:

_____

2. The applicant company has a valid License to Operate as an importer / distributor or manufacturer, with LTO No.____ and valid until _____
3. The said product is not adulterated or misbranded, and contain ingredients and additives that are permitted for use in human food and in accordance with relevant standards, rules and regulations issued by the FDA.
4. As duly authorized person of the _____
   (company name)
   the undersigned has undertaken to be responsible and accountable for the quality, safety of the said food material and shall promptly inform the FDA on any quality or safety issue and concern, including results of laboratory analysis or decision to voluntarily recall or withdraw the product.
5. For the Food Additives, these are listed in the Latest Codex General Standard for Food Additives and/or the Latest Philippine FDA List of Food Additives or other standards recognized by the FDA.
6. He furthermore agrees to post-market surveillance, including inspection of establishment, collection of product samples and laboratory examination.
7. He executed this affidavit to confirm the truth of the foregoing.

IN WITNESS WHEREOF, I have hereunto set my hand this _____ day of _____ at _____.

_____
Affiant

Passport No.
Issued on
Issued at

SUBSCRIBED AND SWORN to before me this _____day of _____ _____ at _____ .

Notary Public

Doc. No. _____
Page No. _____
Book No. _____
Series of 2013