Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2016-007

15 JUN 2016

TO : **ALL FOOD MANUFACTURERS, IMPORTERS, DISTRIBUTORS, EXPORTERS, TRADERS and OTHERS CONCERNED**

SUBJECT : **Notification of Sources for Raw Materials, Low Risk, Medium Risk and High Risk Prepackaged Processed Food Products**

I. BACKGROUND

In the interest of improving business processes in the Food and Drug Administration (FDA), requirements stated in Administrative Order No. 2014-0029 in line with the filing of an amendment for additional sources on License to Operate (LTO) of Food Establishments is hereby repealed upon the implementation of Administrative Order No. 2016-0003 or the "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)" which took effect on 07 March 2016.

In this regard, the Center for Food Regulation and Research (CFRR) acknowledges the importance of the disclosure and declaration of sources of food products as mandated under Republic Act No. 10611 or the Food Safety Act of 2013 for Food Business Operators and Food Safety Regulatory Agencies. Thus, food establishments are hereby instructed to notify their sources of raw materials to be used in the manufacture of prepackaged processed food products and the sources of prepackaged processed food products, themselves, concurrent with the filing of Certificate of Product Registration (CPR) applications following the requirements and procedures stipulated herein until such time that the FDA e-Registration System covering all food products is in full effect through succeeding issuances.

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II. REQUIREMENTS FOR FILING OF NOTIFICATION

1. For Locally Manufactured Products

Notification Letter containing the list of new sources and their complete address, name and the complete address of the manufacturer (in cases when the source is not directly the manufacturer), and distributorship agreement or contract agreement, whichever is applicable, signed by the duly authorized representative of the establishment as reflected in the records of CFRR.

2. For Imported Products

a. Notification Letter containing the list of new sources and their complete address, name and the complete address of the manufacturer (in cases when the source is not directly the manufacturer), and distributorship agreement or contract agreement, whichever is applicable, and signed by the duly authorized representative of the establishment as reflected in the records of CFRR.

b. Certified true copy or certified photocopy of ANY of the following original documents issued to the source by the regulatory or health authority from the country of origin per source:
    i. Valid manufacturer's certificate of registration with Good Manufacturing Practices (GMP) compliance, or its equivalent;
    ii. Valid Phytosanitary Certificate/Health Certificate;
    iii. Valid ISO 22000 Certification;
    iv. Valid Hazard Analysis and Critical Control Points (HACCP) Certificate; or
    v. Certificate of Free Sale.

III. SPECIFIC PROCEDURE IN FILING OF NOTIFICATIONS

Food Establishments engaged in the manufacturing, trading, importation and distribution of the following food product classifications are instructed to observe the following in filing of notifications:

1. For Raw Materials and Low Risk Prepackaged Processed Food Products

The requirement for notification is satisfied by attaching the scanned copies of the abovementioned documents, whichever is applicable, through the

Electronic Registration (E-registration) System during filing of product applications following the procedures as stipulated in FDA Circular No. 2014-029.

2. For Medium and High Risk Prepackaged Processed Food Products

The requirement for notification is satisfied by submitting scanned copies of the abovementioned documents, whichever is applicable, through the Public Assistance, Information and Receiving (PAIR) Unit during filing of product applications following the procedures as stipulated in FDA Circular No. 2014-003.

IV. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in two (2) newspapers of general circulation and submission to the University of the Philippines Office of the National Administrative Register (ONAR).

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OIC, Director General