FDA CIRCULAR
NO._____

Subject: **Supplemental Guidelines on the Management and Conduct of Product Recall for Prepackaged Processed Food Products**

I. BACKGROUND

Pursuant to Rule 14a.6 of Section 14 Article V of Implementing Rules and Regulations (IRR) of Republic Act (RA) No. 10611 or the "Food Safety Act of 2013", the Food Business Operators (FBOs) shall develop their respective product recall program, in accordance with the requirement of the concerned Food Safety Regulatory Agency (FSRA), to handle the products that are not safe or not in compliance with food safety requirements.

Rule 14. b of the same law states that if the FBOs has reason to believe that a food which it produced, processed, distributed, or imported is not safe or not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food from the market and inform the regulatory authority.

It is in this view that FDA Circular (FC) No. 2016-012 or the "Guidelines on Product Recall" was issued to prescribe the general guidelines on the conduct of product recall. It outlines the basic principles, establishes the roles and responsibilities of the Regulator and the Marketing Authorization Holder (MAH), and provides other important provisions in the implementing mechanism.

Consistent with Republic Act No. 8792 or *The Electronic Commerce Act of 2000* in promoting the use of new electronic means to deliver core public services and in the interest of effective and efficient public service delivery, the Food and Drug Administration (FDA) Center for Food Regulation and Research (CFRR), shall implement, the electronic system of notifying recalls by the MAHs to cover mock and product recalls of processed food products. The development of electronic notification will help the MAH in the immediate reporting of food safety concerns and the FDA in performing its oversight of the entire recall process.

Likewise, this FDA Circular is consistent with the provisions of Section J.2. of A.O. 153 s. 2004 or the "Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, Or Holding Food" stipulating that there shall be a written procedure that defines the circumstances under which a recall should be considered. The recall procedure should designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall, and how the recalled material should be treated.

Thus, this Circular is hereby promulgated to supplement and facilitate the conduct of product recall for prepackaged processed food products by providing the MAH with oversight on the development of a recall system.

II. OBJECTIVES

This Circular intends to provide guidelines and procedures on the development of the recall strategy, the conduct of mock recall, and the procedure for the use of electronic recall notification.
Specifically, it aims to:

A. To establish an electronic system of notification of processed food product recalls for the MAH.
B. To provide guidelines to the MAH who shall conduct mock recall or voluntary product recall of processed food products.
C. To support and facilitate ease the submission the implementation of FDA Circular No. 2016-012 entitled *Guidelines on Product Recall* and its future amendments.
D. For facilitation of the MAH's submission of standardized recall status reports to the CFRR-FDA

III. SCOPE

This Circular covers MAHs including Food Manufacturers, Distributors (Wholesaler, Importer, Exporter), and Food Trader who are to conduct a mock recall and those who need to conduct product recalls of registered processed food products under the jurisdiction of the FDA.

This Circular shall **not** cover the following:

A. Unregistered processed food
B. Food products with expired Certificate of Product Registration
C. Processed food that is expired or the label(s) indicates the expiry date; after which the product will not have the quality attributes normally expected by the consumers.
D. Affected processed food products that did not reach the distributors or consumers
E. Fresh or raw food or foods in the primary production and post-harvest stages of the supply chain

IV. DEFINITION OF TERMS

For the purposes of implementing this Circular, the terms used shall be defined as follows:

A. **Consumer-level Recall** refers to the removal of unsafe food from the distribution chain and extends to food sold to consumers.
B. **E-Recall** refers to the web-based electronic notification utilized by the MAH to facilitate the notification to the FDA on the affected food product.

C. **Food Business Operator (FBO)** refers to a person engaged in the food business including one's agents and is responsible for ensuring that the requirements of this Act are met by the food business under one's control.

D. **Food Product Recall Committee (FPRC)** refers to the group created by the FDA, chaired by the Director of the CFRR with members composed of the Division Chief from the CFRR-Licensing and Registration Division (LRD), Division Chief from the CFRR-Product Research and Standards Development Division (PRSDD), Senior Officer form the Food Safety Unit (FSU), Senior Officer from the Common Services Laboratory (CSL), Senior Officer from the Field Regulatory Operations Office (FROO), and FPRC Secretariat from CFRR-PRSDD. The FPRC is responsible for the review of the notifications received from the MAH, the conduct of appropriate communications, overseeing the conduct of recall, and recommending the Recall Order/Termination of Recall of the implicated food products to the FDA Director General.

E. **Mock Recall** refers to the simulation of recall conducted by the FBO to test the effectiveness of the recall procedure.

F. **Recall** refers to a method of retrieval of unsafe, defective, ineffective, and/or grossly deceptive products from the distribution chain.

G. **Recall Team** (RT) refers to the group created by the Market Authorization Holder delegated to investigate, take action, and report the food product recall.

H. **Recall Strategy** refers to a planned course of action to be taken in conducting a recall, it is a written document detailing the MAH's food product recall system such as the depth of recall.

I. **Traceability** refers to the ability to track a product or component forward through specified stages of the supply chain to the consumer, and trace back the history, application, or location of that product or component.

J. **Tracing** refers to the capability to identify the initial source or origin and its characteristics (backward tracing) and eventually its final destination (forward tracing) of any product and from any stage within the value chain.

K. **Tracking** refers to the capability to identify any product at the actual location at any given time.

L. **Trade level Recall** refers to the removal of unsafe food from the distribution chain but does not extend to food sold to the consumer.

M. **Trigger** refers to a process, activity, event or situation that leads to a food product recall. These may come from the activities conducted by the FDA which may include, but not limited to: health product quality/complaints processing; adverse events monitoring; sampling, testing, and verifying of health products; post-licensing inspection, monitoring and investigations; post-evaluation of acknowledged notifications; advertisements and promotional articles monitoring; coordination with regulatory agencies and international partners. Triggers may also come from reports submitted by the MAHs as a result of their post market surveillance activities.

N. **Unregistered processed prepackaged food products** refer to food products with no or expired Certificate of Product Registration from the FDA.

O. **Withdrawal** refers to any measure aimed at preventing a product in the supply chain from being made available on the market.

V. GENERAL GUIDELINES

A. The recall system shall be required for all manufacturers, traders, and distributors (importers, exporters, wholesalers) of processed and prepackaged food products consistent with Rule 14a.6 of Article V of the IRR of RA No. 10611 or the Food Safety Act of 2013. Likewise, it shall be consistent with the provision of A.O. 153 s. 2004 and its amendments and FDA Circular No. 2016-012 and its amendments.
B. Mock recalls may be conducted to simulate and test the effectiveness of established food recall system.
C. The MAH recall system shall be reviewed and revised by the FBO, if necessary, and in accordance with the MAH's work procedures.
D. The MAH has the responsibility to evaluate its recall strategy by conducting a mock recall.
E. A proposed format of worksheet for the recall strategy is available in Annex A as guidance document.
F. The e-recall system shall be used by the MAH to notify the FDA of the food product recalls whether mock recall or product recall.
G. The e-recall system shall facilitate the real-time notification of recall from the MAH to the FDA.
H. The e-recall system shall likewise automatically alert the FDA on the target date of submission of necessary documents from the MAH and the completion date of recall.

VI. SPECIFIC GUIDELINES

A. *Development of a Recall Strategy*
   1. Company Details which include the company name, address, license to operate and activity shall be indicated in the Recall Strategy as this presents ownership of the recall strategy. (see Annex A.1 Company Details).

   2. Identify the food product
      a. To facilitate the product recall, complete details of the implicated finished product shall be indicated in the recall strategy.
      b. A label and a clear picture of the implicated products as sold in the market from different angles shall also be included. (see Annex A.2 Product Information).

   3. Creation of a Recall Team (RT)
      a. For the MAH without an existing RT, it is necessary that a team be created specifically to handle recalls. The MAH shall also consider the number of

members of the RT on the number of existing personnel within the organization (see Annex A.3 Recall Team).

b. Team members shall be chosen according to their expertise and training.
c. The RT shall consist of people from different areas of the organization which may include but not be limited to Production, Quality Control, Purchasing, Sales and Marketing, Legal Services, Distribution and Supply chain, and Public Relations.
d. It is necessary that the team should comprise of different individuals from different areas to be able to effectively implement their responsibilities such as decision making, quality assurance/technical advisory, media communication, complaint investigation, contacting accounts, regulatory contact, legal counsel, review and evaluation of the Recall plan, Appointment of a Recall Coordinator responsible for the activities of the recall procedure.
e. The team shall likewise create a directory which shall include details such as the name of the RT member, Alternate RT member (if applicable), Mobile Number and e-mail address of each member and alternate. Moreover, the directory shall be regularly updated. (see Annex A.3 Recall Team).
f. The RT shall conduct an evaluation of the recall strategy, address, and immediately correct errors or observed gaps, and monitor the recall process.

4. Conducting Health Hazard Evaluation (HHE) (see Annex A.4 Health Hazard Evaluation Checklist) and Establishing the Decision to Recall.
   a. Once a trigger is received it shall be conveyed to the team to conduct HHE. The MAH shall conduct the HHE to determine whether the implicated product is subject for recall since the risk management option shall depend on the result of the HHE and to be able to identify the recall classification. Moreover, the result of the HHE shall be documented by the team.
   b. If based on the HHE, the subject food product has a safety issue that warrants recall of such product, the recall strategy shall be executed. The distribution of the implicated product shall be halted, while the RT shall conduct product tracing to determine the depth of the recall.
   c. Recall Instructions for the distributors/retailers of the implicated product shall be immediately provided during the notification of the recall (Annex A.5 Recall Instruction).

5. Conduct of Traceability and Determination of Depth of Recall
   a. The MAH shall conduct tracing of the product to be able to determine the root cause of the risk event. Details may include Raw Material Identification, Supplier name and address, Batch/Lot number, Registration Number, Expiration date, Manufacturing date.
   b. Tracking shall also be conducted to the finished product. A list of distributors/retailers of the implicated shall be prepared by the MAH and provided to the RT. An effective recall shall entail complete record of the distribution of the finished product which may include Distribution Records, Distributor/Retailer Name and Address, Name of Contact Person,

Contact Number and Email Address. (see Annex A.6 Distributor List Worksheet).

c. Traceability activity shall also include the documentation during the work-in-process and rework.
d. The depth of recall shall depend on the scope of the distribution of the products resulting from the conduct of tracking of the product.

6. Recall Notification
   a. MAH shall notify all the distributors/retailers/consignees included in the list. (see Annex A.6 Distributor List Worksheet)
   b. MAH shall utilize all modes of communication to reach the distributors/retailers/consignees on the list. This may include phone call, letter, electronic mail, and other media platforms. Where appropriate, public notification may also be conducted through the company platforms of communication.
   c. Phone/message scripts shall be prepared to provide clear instructions to the distributors/retailers/consumers during the recall communication. (see Annex A.7-8 Company Recall Notification, Phone Script)
   d. The MAH shall document the conduct of recall notification. (see Annex A.9 Recall Notice Worksheet).
   e. Recall notification method is effective once all the distributors/retailer/consumers in the list were notified and immediately responded to the instructions of the MAH.

7. Recall Effectiveness Check
   a. The effectiveness check shall be conducted by the MAH to verify that all distributors/retailers/consumers of the implicated product at the recall level (whether Trade Level Recall or Consumer Level Recall) received the company notification about the recall and have taken appropriate action (Annex A.10 Recall Effectiveness Check Questionnaire).
   b. Effectiveness check is also conducted through several methods which may include but are not limited to mail, telephone calls, company visit, or online platform. It may also include combinations of these methods following the same set of questionnaires for uniformity.
   c. The MAH shall document the responses of the distributors/retailers/consumers in the recall effectiveness check.
   d. Effectiveness checks shall be conducted to all the distributors/retailers of the implicated product. However, if the distributors/retailers/consumers reported not having in their possession the implicated products, effectiveness check is no longer applicable.
   e. Recall is effective when all of the implicated products have been documented, traced and tracked, and proper disposition conducted.

8. Disposition of the implicated products shall follow FDA Circular 2016-012 and its future amendments.
   a. The recall strategy shall specify the method and type of disposal of the implicated products.
   b. The MAH shall request the FDA for Food-Drug Regulation Officer to witness the destruction of the recalled products to provide feedback report.

c. The MAH shall submit the final reports on recall status (see Annex A.11 Recall Status Report) and of the conduct of the disposal to be reviewed by the FPRC as basis for the termination of the recall.(see Annex A.12 Request Form).

B. Conduct of Electronic Recall Notification through the FDA website

1. The notification of the MAH to the FPRC shall be made at the earliest opportunity once a decision has been made that a product is deemed for recall.
2. All the available documents shall be submitted during the notification by the MAH, other relevant documents necessary for evaluation may be submitted once available (e.g., Recall Status Report).
3. The notification shall provide information on the details of the recalling company, manufacturer (as applicable), recall coordinator, product for recall, reason for recall, and summary of the health hazard evaluation as specified in the Annex B of this Circular.
4. Other attachments may include but not limited to test reports, label, package inserts or directions for use.
5. Specific instruction on the notification is stipulated in the Annex B Notification Procedure of this guideline.
6. The conduct of mock recall may also be notified using the same system.

VII. REVIEW AND EVALUATION

The CFRR shall review and evaluate the FDA Circular after 3 (three) years of its effectiveness and implementation to determine whether the policy's objectives, impact and effectiveness are achieved. Moreover, the

VIII. SEPARABILITY CLAUSE

If any part, term, of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

IX. EFFECTIVITY

This Circular shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.

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Director General

DTN: 20221223101949