FDA CIRCULAR
No. 2024-004

07 MAY 2024

SUBJECT: Guidelines on the Issuance of FDA Import Permit as "Samples Only" for Prepackaged Processed Food Products Intended for Research and Development

I. BACKGROUND

It is the policy of the State as embodied in Article II of the 1987 Constitution to protect and promote the right to health of the people and in Section 12, Article XIII of the same regulation to establish and maintain an effective food and drug regulatory system. In the implementation of the foregoing, Section 5 (o) of R.A. 9711 amending Section 4 (b) of R.A. 3720, as amended, by E. O. 175, authorizes the FDA to prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing activities about the health products as covered in this Act.

In accordance with Republic Act (RA) No. 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009", the FDA shall have the power and function to regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products. and to develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products.

In view thereof, the Center for Food Regulation and Research (CFRR), through this issuance must have a prescribed standards and regulations that shall provide guidelines and obligate the concerned establishments to secure Import Permit prior to importation of prepackaged processed food products, bulk foods and raw materials intended as samples for research and development purposes.

II. OBJECTIVE

This Circular aims to set and provide guidelines on the process of securing FDA Import Permit as "Samples Only" for Prepackaged Processed Food Products.

III. SCOPE

A. This issuance covers all Food Business Operators (FBOs) with License to Operate (LTO) as Food Manufacturer/Importer, Food Trader/Importer, Food Distributor/Importer that engage in the importation of food samples to be used for research and development purposes (e.g., plant/production trial, sensory evaluation and quality assurance purposes within the premises of food establishment and its employees) or testing of unregistered imported processed food products, food trade fairs and exhibitions, and for donation.

B. This issuance shall not cover the following:

1. Importation of products intended for "free tasting" during exhibits and trade shows;
2. Processed food products intended for distribution, sale, or offer for sale as prescribed in the FDA Memorandum Circular No. 2013-032, entitled, "Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs"; and.
3. Market testing to consumers or in any commercial facilities for market or consumer acceptability.

IV. DEFINITION OF TERMS

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

A. **Bulk Food Materials** – refers to raw materials, ingredients, and food additives that are packed in wholesale containers, either for food industry use, institutional use, food service, or catering business. Generally, not intended for commercial distribution.

B. **Establishment** - refers to a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

C. **Finished goods / products** - refers to goods that have completed the manufacturing process, but have not yet been sold.

D. **Food Business Operator** - 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.

E. **Import** - refers to the distribution of products to a local destination by crossing international borders.

F. **Import Permit** - refers to a form of authorization issued by the FDA to an establishment to import a prepackaged processed food, bulk food and raw materials in the Philippines for the purpose of research and development and shall not be intended for market testing purposes.

G. **Importer** - refers to any establishment that imports raw materials, ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

H. **Market Authorization Holder (MAH)** - refers to the company, corporate or legal entity that is responsible for all aspects of the product, including quality and compliance conditions of the marketing authorizations.

I. **Market testing -** refers to the displaying and offering of products or samples to the consumers for sensory evaluation to test the market acceptability.

J. **Prepackaged -** refers to packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.

K. **Processed Food** - refers to food that has been subjected to some degree of processing like milling, drying, concentrating, canning, or addition of some ingredients which changes partially or completely the physicochemical and/or sensory characteristics of the food's raw material.

L. **Raw materials** – refers to all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as a finished product. Raw materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single component.

M. **Sensory Panel -** refers to the food establishment's group of trained testers/ assessors who have exceptional sensory faculties and can describe the products according to the basis of sensory attributes (i.e., taste, smell or feel)

V. GENERAL GUIDELINES

A. All FBOs which are covered under Section III. A. of this Circular shall secure an Import Permit from FDA prior to importation of unregistered food products for the purposes of research and development or testing, food trade fairs and exhibitions, and for donation.

B. All imported processed food products intended for research and development are prohibited from market testing to consumers or for display in any commercial facilities, trial run or actual selling of products.

C. Imported products for taste testing shall only be participated by the sensory panel employed by the concerned food establishment.

D. The maximum limit (in net weight) for imported products (per Invoice) intended as samples per variant or type is as follows:

1. Raw Materials: 50 kilograms or 50L
2. Acceptable Food Additives: 5 kilograms or 5L
3. Finished Products: 50 kilograms per variant / item and per invoice.
4. Food Supplements: 5 kilograms per variant (in form of capsule, powder or tablets) and per invoice.

E. Applications for Import Permit shall be applied to FDA at least fourteen (14) days before the arrival of product samples. Applications filed less than 14 days before the arrival of the product samples can still be accepted but the Market Authorization Holder (MAH) shall take full responsibility for any possible

consequences in case the permit is not released before the samples arrive at the port.

F. Two (2) original copies of Import Permit shall be issued per Sales/Proforma Invoice regardless of the declared number of imported products. Payment shall be required for an additional copy of the Import Permit.

G. Payment of Import Permit shall be made per Sales/Proforma Invoice. The payment for the import permit shall be based on the current FDA schedule of fees and charges and its latest revision.

H. Should the applicant fail to comply with the issued Notice of Deficiency (NOD) on a given period, a Letter of Denial shall be issued by the Center Director.

I. The payment for disapproved applications shall automatically be forfeited. Disapproved applications may be re-applied upon payment of the corresponding fees and submission of documentary requirements.

VI. SPECIFIC GUIDELINES

1. Requirements

Application for Food Samples

Submit one (1) scanned copy of the following required document:

1. Application Letter or Letter of Intent stating the following information:
    a. Identification/Enumeration of each article of food in the shipment
    b. Brand Name and/or Product Name
    c. Quantity
    d. Manufacturers' Name and Address
2. Notarized Affidavit of Undertaking (See Annex B)
3. Certificate of Analysis or Certificate of Free Sale or Health Certificate
4. Sales/Proforma Invoice
5. Proof of Payment of Fees as prescribed by current FDA regulations
6. Valid License to Operate as Manufacturer/Importer or Distributor/Importer or Trader/Importer
7. The FDA may require additional document/s on products that are considered high-risk provided that the reason is to address uncertainties on safety as deemed necessary.
8. Packing list
9. Bill of Landing/ Airway Bill (if available)

Application for Donated Food

Submit one (1) scanned copy of the following required document:

1. BIHC Endorsement Letter
2. Letter request from Donee
3. Certificate of Quality (should reflect the expiration or last recommended date of consumption) / Certificate of Free Sale

4. Certificate of Donation
5. Deed of Acceptance
6. Invoice Packing List
7. Bill of Lading/Airway Bill (if available)
8. Payment (Php 510.00/inclusive of 1% LRF)

Application of Import Permit for Exhibits

Submit one (1) scanned copy of the following required document:

1. Application Letter stating details of the exhibit (date, venue, event name), products to be imported and their quantity
2. Notarized Affidavit of Undertaking (see Annex C);
3. Certificate of Analysis (E.g. physical, chemical, microbiological and nutrient analysis of the finished product) or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by a recognized institutions or duly authenticated by the Philippine Consulate from the country of origin;
4. Proforma or Commercial Invoice;
5. If available, these documents may be attached to the application dossier: Packing List, Airway Bill or Bill of Lading; and
6. Proof of Payment of Fees as prescribed by current FDA regulations and its future

2. Procedure for the Application of Import Permit

1. The applicant company shall submit the application to the Food and Drug Action Center (FDAC) through email at fdac.letters@fda.gov.ph .The subject of the email shall follow the format: CFRR: Import Permit, Company.

2. FDAC shall issue an Acknowledgement Receipt and 14-digit Document Tracking Number (DTN) as reference for payment of the applicant.

3. The applicant company shall pay the assessed fee through any FDA Authorized means (e.g. Landbank LinkBiz).

4. The applicant company shall sends the proof of payment to FDAC through email. All applications for import permits shall be in pending status until the proof of payment is received, validated and posted at the FDA Document Tracking System by the FDA Cashier.

5. FDAC forwards the application to CFRR receiving and FDAC will update the FIS indicating that the application is transmitted to CFRR. Received applications shall be referred to the assigned CFFR Evaluator.

6. The CFRR Evaluator shall evaluate the correctness of documents and updates the FIS indicating that the application is forwarded to checker for quality assurance. Should the Applicant fail to submit the correct requirements, a NOD shall be issued to provide the specific nature of the deficiency. A compliance period of five (5) working days shall be given to the applicant to comply with the NOD.

7. The CFRR Checker shall review if the recommendation is appropriate and updates the FIS indicating that the application is forwarded to the Center Director. The Center Director renders the final decision on the recommendation.

8. The CFRR personnel forwards the Permit/Authorization to Records section for release and updates the FIS indicating the same.

9. Company applicant may track the status of the application through the FDA Kiosk (https://www.fda.gov.ph/kiosk/) and the processing time of each steps of applications through the 2024 Citizen's Charter of CFRR or its latest revisions through the FDA website.

3. Grounds for Disapproval of Applications

1. Failure to submit complete or correction to documentary requirements.
2. Failure to respond to notice of deficiency or to submit documents on time.
3. Misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law or this issuance.
4. Such other analogous grounds or causes as determined by the FDA in accordance with RA 9711, RA 10611 and other pertinent policies.

4. Validity of Import Permit

The Import Permit shall be valid for ninety (90) days from the date of its issuance and shall be used only once.

5. Authorization of Import

1. The Director, Center for Food Regulation and Research, by Authority of the Director General, shall issue an Import Permit addressed to the Commissioner, Bureau of Customs (BOC).
2. The original Import Permit issued by the FDA shall be presented and surrendered to the Bureau of Customs through the BOC Examiner.

VI. MONITORING AND REVIEW CLAUSE

This FDA Circular shall be reviewed and evaluated within three (3) years of its implementation to determine whether the policy's objectives, impact, and effectiveness are achieved.

VII. 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.

VIII. EFFECTIVITY

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

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Director General

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