FDA CIRCULAR
No. _____

SUBJECT: **Rules and Guidelines on the Issuance of Import Permit as "Samples Only" for FDA Regulated Products Intended for Research and Development Purposes**

I. BACKGROUND

It is the policy of the State as embodied in Article II, Section 15 of the 1987 Constitution to protect and promote the right to health of the people and in Section 12, Article XIII of the 1987 Constitution to establish and maintain an effective food and drug regulatory system. In the implementation of the foregoing, Section 15 (2), Chapter (4) Title IX, Book IV of the Administrative Code of 1987 authorizes the Food and Drug Administration to act as the policy formulation and sector monitoring arm of the Secretary of Health on matters pertaining to food, drugs, traditional medicines, cosmetics and household products containing hazardous substances. Further, the Center for Food Regulation and Research (CFRR) in accordance with Republic Act No. 9711 "*shall 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.*"

In view thereof, the Center for Food Regulation and Research (CFRR), through this issuance, obligates 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. OBJECTIVES

The objective of this Circular is to set and provide the guidelines on how to secure Import Permit as "Samples Only" from FDA - CFRR.

III. SCOPE

This issuance covers food establishments with License to Operate as Food Importer with food manufacturing activity processing food for its own use, food trader with contract to a toll manufacturer and food distributor/wholesaler engaged in the importation of food samples to be used for research and development purposes i.e. plant/production trial, sensory evaluation and quality

assurance purposes within the premises of food establishment and its employees, it does not cover market testing to consumers or in any commercial facilities for market or consumer acceptability.

This issuance shall not cover importation of products intended for use during exhibits and trade shows.

IV. DEFINITION OF TERMS

1. **Establishment** means 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.

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

3. **Import** refers to distribution into a local destination by crossing international borders.

4. **Import Permit** refers to a form of authorization issued by the FDA to an establishment to importation of 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.

5. **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.

6. **Sensory Panel** refers to the food establishment's group of trained testers who have exceptional sensory faculties and can describe products on the basis of taste, smell or feel. They are trained to describe their sensory experience using words generated from training sessions – these words are more detailed than those used by consumers and more useful for the research and development department.

7. **Market testing** refers to displaying and offering of product or sample for sensory tests to consumers to test market acceptability. Market testing is covered by ads and promo permit hence, not applicable to import permit.

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

V. GUIDELINES

A. General Guidelines

1. FDA-regulated establishments with LTO as Food Importer / Distributor and/or Food Importer / Trader shall apply for import permits to import unregistered food products sent through air, mail or sea transport for purposes of research and development and not intended for market testing purposes.

2. The importation of food products shall be used exclusively by the manufacturer/importer, trader/importer, or distributor/importer for research and development of its own product or for sample to another establishment registered.

3. Applications for Import Permit shall be applied at least 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.

4. One (1) original copy of import permit shall be issued per Sales/Proforma Invoice regardless of the number of imported products declared. Additional payment is required for another copy of the import permit.

5. Payment of import permit shall be made per Sales/Proforma Invoice. The payment for the import permit shall be based on the prevailing FDA schedule of fees and charges.

6. Should the applicant fail to meet the requirements for issuance of import permit, a Letter of Disapproval (LOD) shall be issued by the Center Director following a compliance period of seven (7) calendar days. The Notice of Deficiency shall specify the nature of deficiency.

7. 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.

8. For this purpose, the imported 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. Market testing is regulated under Ads and Promotion Permit.

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

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

- **a.** Raw Materials: 50 kilograms or 50L
- **b.** Acceptable Food Additives: 5 kilograms or 5L
- **c.** Finished Products: 50 kilograms per variant / item and per invoice.
- **d.** Food Supplements: 5 kilograms per variant (in form of capsule, powder or tablets) and per invoice.

B. Specific Guidelines for Application of Import Permit

1. The applicant company shall submit the application to 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 Acknowledgement Receipt and 14-digit Document Tracking Number (DTN) as reference of the applicant. Received applications will be referred to CFFR Pre-assessor.

3. An authorized CFRR personnel shall pre-assess the submitted application and documentary requirements based on its completeness. Approval of pre-assessed application does not automatically mean an approved import permit. The application is still subject for evaluation and review of authorized CFRR evaluator.

4. An email shall be sent to the company representative and an update at the Document Tracking System informing him/her of the result of the pre-assessment.
    a. If the application is denied in the pre-assessment, the applicant will be advised to secure a new DTN to submit the application for another pre-assessment. The use of old DTN shall not be allowed in resubmission of applications for pre-assessment.
    b. If the application satisfactorily passed the pre-assessment, the applicant will be advised to proceed with the payment and to provide proof of payment of fees to cashierposting@fda.gov.ph.

5. All applications for import permit shall be on pending status until the proof of payment is received, validated and posted at the FDA Document Tracking System by the FDA Cashier.

6. Once the payment is posted, applicant company shall email the copy of the pre-assessed application, proof of payment and approved Pre-assessment Form to fdac.letters@fda.gov.ph.

7. FDAC shall transmit received applications to CFRR Receiving personnel for evaluation and review.

8. Applicant company may track the status of the application through the FDA Kiosk (https://www.fda.gov.ph/kiosk/)

C. Requirements

The requirements for issuance of Import Permit are specified in Annex A of this issuance.

D. Grounds for Disapproval of Applications

The following shall be grounds for disapproval of an application:

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.

E. Validity of Import Permit

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

F. 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.
2. The original import permit issued by FDA shall be presented and surrendered to the Bureau of Customs through the BOC Examiner.

VI. REPEALING CLAUSE

All other circulars, memoranda and other related issuances inconsistent or contrary to the provisions of this FDA Circular are hereby repealed accordingly.

VII. EFFECTIVITY

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

DR. SAMUEL A. ZACATE
Director General, Food and Drug Administration

DTN **20161017170836**

ANNEX A

Requirements for Application of Import Permit

A. Requirements for Products Intended for Product Research and Testing
The following are the requirements for application by an establishment.

1. Application Letter or Letter of Intent stating the following information:
   1.1. Identification/Enumeration of each article of food in the shipment
   1.2. Brand Name and/or Product Name
   1.3. Lot Identification Code or Sampling Code or Product Research Code
   1.4. Quantity
   1.5. Manufacturer's 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.

ANNEX B

Affidavit of Undertaking

I, (Name of Applicant) of legal age, (Position in the Company) and/or duly authorized representative of (Name of Company and Address as declared in the License to Operate), after having been sworn in accordance with law, hereby declare that:

1. The (Company Name) has imported products from (Country of Origin).

2. The said importation is covered by Proforma Invoice No. _____dated _____ of (Source of the Importer).

3. The applicant company has a valid License to Operate as an importer, with LTO No. _____ valid until _____ covering the said shipment.

4. The products are not adulterated, nor misbranded, and contain ingredients and additives that are permitted for use in humans and in accordance with relevant regulations issued by FDA.

5. The said product/s is for use by (Company Name) for (State Purpose) Moreover, it will not find its way in the market for sale or for distribution.

6. The company understands and agrees that the products may be subjected to FDA Laboratory examination at any time to verify the food product safety and quality and that the cost of laboratory examination shall be charged to the importing company.

7. This Affidavit is executed to confirm the truth of the foregoing.

IN TRUTH WHEREOF, I am affixing my signature below this _____ day of _____, 20___ at _____.

_____
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Affiant Name

SUBSCRIBED AND SWORN TO BEFORE ME, this _____ day of _____, 20___ at _____. Affiant exhibited to me his/her (Government Issued ID and Number).

Notary Public

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