FDA Circular
No. _____

SUBJECT: **Guidelines on the Importation and Exportation Notification for Pharmaceutical Products and Raw Materials**

I. RATIONALE

Republic Act (RA) No. 3720, as amended by RA No. 9711, otherwise known as the "Food and Drug Administration (FDA) Act of 2009", mandates the FDA to regulate and subsequently issue appropriate authorizations to establishments engaged in the manufacture, distribution, importation, exportation and retailing of health products, among others. Also, Section 5 of RA No. 9711 declares the following powers of the FDA, *"(b) to assume primary jurisdiction in the collection of samples of health products; (c) to analyze and inspect health products in connection with the implementation of this Act; (l) to strengthen the post-market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products; and (p) to maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the Director-General for confiscated goods in strategic areas of the country especially at major ports of entry."*

Further, Section 23 of Executive Order No. 175 s. 1987 which amended Section 30 of RA No. 3720, states that *"The Commissioner of Customs shall cause to be delivered to the Bureau samples taken at random from every incoming shipment of food, drugs, devices, and cosmetics which are being imported or offered for import into the Philippines, giving notice thereof to the owner or consignee."* In addition, Article I Section 6 (Requirements for Every Incoming Shipment of Health Products) of the Book II of the Implementing Rules and Regulation (IRR) of RA No. 9711, states that "*The FDA in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to importation of health products such as, but not limited to, sampling and examination, in accordance with relevant existing laws and regulations, of every incoming shipment of health products"*. In order to effectively regulate importation activities on health products, inter-agency cooperation needs to be well-established.

To implement this, FDA Memorandum Circular (FMC) No. 2013-032, entitled "Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs", was issued, wherein only valid FDA License to Operate (LTO) and Certificate of Product Registration (CPR) were required to be presented to the Bureau of Customs (BOC) for the release of pharmaceutical products. However, there is a need to strengthen market control within the distribution chain through measures to ensure that the public only receives quality-assured pharmaceutical products. The infiltration of substandard and counterfeit pharmaceutical products into the supply system shall be prevented through risk-based surveillance schemes and rigorous control. Therefore, as part of the FDA's powers and functions under RA No. 9711, requiring the concerned pharmaceutical establishments to notify each

importation/exportation of pharmaceutical products and raw materials is necessary to strengthen the FDA's overall market surveillance and control regulatory function.

In the interest of public health, importation and exportation activities relative to pharmaceutical products and raw materials shall be regulated and monitored by the FDA. Hence, issuance of this Circular is imperative in ensuring consistency and effectiveness of these regulatory activities.

II. OBJECTIVES

This Circular aims to achieve the following:

A. Provide detailed guidelines and clear procedures in the notification process of importation and exportation of pharmaceutical products and raw materials.

B. Establish and identify the authorized ports of entry and exit of pharmaceutical products and raw materials into and out of the country for effective border control.

III. SCOPE

This Circular shall apply to all FDA-licensed pharmaceutical establishments engaged in the manufacture, importation, and exportation of finished, semi-finished products or raw materials of pharmaceutical products for human and veterinary use, except for pharmaceutical products for personal use covered under DOH-FDA-BOC Joint Circular No. 1 s. 2015.

This Circular shall also apply to Sponsors and Contract Research Organizations (CRO) for investigational pharmaceutical products, and to Compassionate Special Permit (CSP) Holders and Donee/Recipient/Consignee for pharmaceutical products for compassionate use and donation, respectively.

IV. DEFINITION OF TERMS

All the terms or words used herein that are already defined under RA No. 3720 as further amended by EO No. 175 and RA No. 9711, other related FDA-implemented health laws and their respective IRRs, for the purpose of implementing this Circular, shall have the same meaning as defined therein. In addition, the following terms shall be defined as follows for the purpose of this issuance:

A. **Air Way Bill (AWB**) refers to a transport document for airfreight, used by airlines and international freight forwarders, which specifies the holder or consignee of the bill who has the right to claim delivery of goods when they arrive at the port of destination. It is a contract of carriage that includes carrier conditions, such as limits of liability and claims procedures. In addition, it contains transport instructions to airlines and carriers, a description of the goods, and applicable transportation changes.

B. **Bill of Lading (B/L)** refers to a transport document issued by shipping lines, carriers, and international freight forwarders or non-vessel operating common carriers for water-borne freight. It is a contract of carriage between the carrier and the shipper which defines the liabilities of each party. The holder or consignee of the bill has the right to claim delivery of the goods at the port of destination. It may refer to a Master Bill of Lading or a House Bill of Lading.

C. **Bureau of Customs (BOC)** refers to the national agency under the Department of Finance in charge of imports, exports, and foreign trade. The mandate of BOC is to implement an effective revenue collection by preventing and suppressing smuggling and the entry of prohibited imported goods. It supervises and controls the entrance of vessels and aircraft engaged in foreign commerce. It also enforces the Tariff and Customs Code of the Philippines and all other laws, rules and regulations related to Tariff and customs administration.

D. **Commercial Invoice** refers to a legal document between the supplier and the customer that clearly describes the sold goods, and the amount due on the customer.

E. **Compassionate Special Permit (CSP) Holder** refers to a qualified institution or qualified licensed physician who has applied before the FDA and has been granted the CSP.

F. **Finished Pharmaceutical Product** refers to a pharmaceutical product that has undergone all stages of production and quality control, including packaging in its final container and labeling.

G. **Law Enforcement Agencies (LEAs)** refer to agencies responsible for enforcing the law, particularly the activities of prevention, detection, and investigation of crimes and the apprehension of the criminals or offenders.

H. **Packing List** refers to the itemized list of articles usually included in each shipping package, giving the quantity, description and weight of the contents.

I. **Proforma Invoice** refers to a draft invoice given by the shipper to a recipient/consignee prior to the shipment of goods. It provides information on the nature, quantity, value and weight of goods to be imported.

J. **Raw Material** refers to all substances whether active or excipients that are employed in the processing of a finished pharmaceutical product.

K. **Semi-finished Pharmaceutical Product** refers to a pharmaceutical product that is obtained during the manufacturing process, and that, with further processing, can become a finished pharmaceutical product.

V. GENERAL GUIDELINES

A. A notification must be submitted for every shipment and all batches/lots of pharmaceutical products or raw materials covered by this guideline. The following entities/establishments with valid FDA-LTO and CPR/authorization of the pharmaceutical product or raw materials, if applicable, shall notify the FDA of all of their importation/exportation activities:

Establishment	Pharmaceutical product
Manufacturer, Trader	Raw material, semi-finished pharmaceutical product
Distributor/Importer/Exporter	Finished pharmaceutical product, Investigational pharmaceutical product
Sponsor, CRO	Investigational pharmaceutical product
CSP Holder (Institution/Physician)	Pharmaceutical products under CSP
Donee/Recipient/Consignee	Donated pharmaceutical product

B. All notifications shall be filed within one month (1 day to 30 days) prior to the arrival/departure of the shipment to/from the Philippines.

C. The pharmaceutical establishments, including the CSP Holders and donees/recipients/consignees, shall submit documentary requirements to support the notification through the FDA eServices Portal System. The applicants shall undertake responsibility for the submission of complete and correct application documents to the FDA, in accordance to the list of requirements and acceptable equivalent document stipulated by the guidelines. The FDA eServices Portal System for this process shall accept notifications during the operating period of FDA Online Services.

D. The pharmaceutical establishment shall indicate the date of arrival/departure at their chosen port of entry/exit in the notification. Importation/Exportation of pharmaceutical products and raw materials shall be channeled exclusively through the established and identified Bureau of Customs (BOC) port listed in Annex A. Should there be changes in the port of entry/exit (i.e. due to port congestion), the pharmaceutical establishment shall amend their previous notification.

E. The Notification Acknowledgement shall be issued through the official email to the pharmaceutical establishments after the successful submission of notification through the FDA eServices Portal System.

F. The list of pharmaceutical products and raw materials notified for importation and exportation shall be posted in the FDA Verification Portal System.

G. Following the existing regulations, the BOC shall process and release the importation or exportation shipment without the need to present the notification acknowledgment but upon presentation of the FDA authorizations cited below:

Authorization	Type
Valid LTO and CPR	Pharmaceutical products for distribution

Valid LTO and Import License	Investigational pharmaceutical products
Valid CSP	Pharmaceutical products for compassionate use
Valid CPR for Donation	Pharmaceutical products for donation

H. BOC ports and third-party warehouses shall be inspected by the FDA to ensure compliance with Good Distribution and/or Storage Practices (GDP/GSP) and other relevant existing rules and regulations.

I. The FDA shall conduct risk-based post-marketing surveillance activities upon arrival/departure including but not limited to collection of pharmaceutical product samples for testing, inspection of involved establishments/ facilities, collaboration with BOC and Law Enforcement Agencies (LEAs), and other regulatory actions as necessary.

J. The foregoing general guidelines are nonexclusive and shall not preclude the FDA from performing other regulatory and enforcement activities, and the covered establishments to allow inspection of their regulated activities and collaborate with the FDA authorities on action taken for consumer protection, as may be authorized by law, other rules, and regulations.

VI. SPECIFIC GUIDELINES

A. Documentary Requirements

1. The required details of the LTO, CPR and local GMP Certificate issued by the FDA shall be encoded, and the following documentary requirements both for import and export of finished, semi-finished pharmaceutical products and raw materials shall be uploaded to the FDA eServices Portal System:
    a. Certificate of Analysis (COA), if available
    b. Proforma Invoice/Commercial Invoice
    c. Packing list, if applicable

2. The required details of the LTO and Import License issued by the FDA shall be encoded, and the proforma invoice/commercial invoice shall be uploaded to the FDA eServices Portal System both for import and export of investigational pharmaceutical products.

3. The required details of the CSP issued by the FDA shall be encoded to the FDA eServices Portal System for importation of pharmaceutical products for compassionate use.

4. The required details of the CPR issued by the FDA for importation of pharmaceutical products for donation shall be encoded to the FDA eServices Portal System.

B. Notification Process

1. Guidelines on notification using FDA eServices Portal System are provided in Annex B and the procedure on the use of the FDA eServices Portal System for Notification of finished, semi-finished pharmaceutical products and raw materials is provided in Annex C.

2. Procedure on the use of the FDA eServices Portal System for Notification of investigational pharmaceutical products, and pharmaceutical products for compassionate use and donation shall be released on separate issuances.

3. In case where the cause of delay is due to force majeure or fortuitous events which result to damage or destruction of documents, and/or system failure of the computerized processing, other official modes of notification (i.e., registered mail or personal delivery) shall be resorted to and the prescribed processing times shall be suspended and appropriate adjustments shall be made, provided the same shall be made known to the affected applicants or stakeholders.

C. Post-Notification Commitments

All entities/establishments with notification for importation and exportation of pharmaceutical products, raw materials, investigational pharmaceutical products, and pharmaceutical products under CSP and donation, shall be required to input and submit the following within fifteen (15) working days from the arrival/departure of the shipment, through the FDA eServices Portal System, as post-notification commitments:

1. Date of Arrival/Departure of the pharmaceutical products
2. Bill of Lading/Airway Bill
3. Certificate of Analysis (COA), if not provided during the notification process for finished pharmaceutical products/raw materials

Procedure on the Use of the FDA eServices Portal System for Post-Notification Commitment is provided in Annex D. Noncompliance with the submission of post-notification commitments shall result in regulatory action without prior notice.

D. Inspection of BOC Ports and Third-Party Warehouses

1. All the identified designated BOC ports and third-party warehouses to be used for the importation and exportation of pharmaceutical products and raw materials shall be inspected.

2. Designated ports shall have secured storage facilities, including cold storage areas. The FDA and BOC shall ensure that the appropriate environmental conditions are maintained for storage, and monitor that the equipment is maintained and in good working order.

3. Inspections shall be done by the FDA to ensure compliance with GDP/GSP and other relevant existing rules and regulations.

E. Post-Marketing Surveillance

1. The FDA in coordination with BOC, following a risk-based approach, shall collect pharmaceutical products and raw materials based on established procedures and subject the sample to physical and chemical analysis. The consignment will be released from the BOC but shall be inspected in the MAH warehouse

2. All unauthorized shipments and shipments containing unauthorized pharmaceutical products and raw materials, shall be seized by the BOC, in coordination with FDA, and hold the shipment for further investigation.

3. The FDA shall ensure that the BOC has access to the FDA eServices Portal System for verification of the importation/exportation notification.

4. The FDA shall collaborate with the BOC and LEAs for the relevant investigation and legal actions, when necessary.

5. The FDA shall inspect involved establishments/entities and take necessary regulatory actions against violative products and establishments/entities.

VII. REGULATORY ACTION

Noncompliance with the provisions of this Circular will subject the product and establishment/entities to stricter post-marketing surveillance and appropriate regulatory actions.

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 CLAUSE

This Circular shall take effect fifteen (15) days after its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines-Office of the National Administrative Register (UP-ONAR).

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Director General