FDA Circular
No. _____

SUBJECT: **Guidelines for the Notification of All Importation and Exportation of Finished Drug Products and Raw Materials**

I. RATIONALE

Republic Act (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."

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".*

The FDA hereby issued FDA Memorandum Circular (FMC) No. 2013-032 wherein a valid License to Operate (LTO) and Certificate of Product Registration (CPR) are required for the release of drug products. However, there is a need to strengthen market control within the distribution chain through measures to ensure that the public only receive quality-assured drug products. The infiltration of substandard and falsified drug 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 drug establishments to notify each importation/exportation of drug products and raw materials is necessary to strengthen the FDA's overall market surveillance and control regulatory function.

In the interest of public health, import/export activities related to drug products need to be controlled and under the proper oversight of the FDA. Issuance of this guidelines is imperative to ensure the 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 for finished drug products and raw materials.

B. Establish the authorized ports of entry and exit of finished drug products and raw materials into the country

C. Conduct of inspection of entry/exit ports authorized by the Bureau of Customs (BOC) for finished drug products and raw materials.

III. SCOPE

This Circular shall apply to all FDA-licensed drug establishments engaged in the manufacture, importation and exportation of finished drug products or raw materials intended for commercial distribution.

This Circular shall not cover drug products and raw materials used in clinical trials/product development/research, drug products for personal use, donations, and under Compassionate Special Permit, which shall be processed based on existing rules and regulations.

IV. DEFINITION OF TERMS

For the purpose of this issuance, the following terms shall be defined as follows:

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 od 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, the amount due on the customer.

E. **Drug**, which may also be termed as **drug product**, **pharmaceutical product**, or **medicinal product,** refers to chemical compound(s) or biological substance(s), other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals, including the following:
   1. any article recognized in official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA;
   2. any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
   3. any article, other than food, intended to affect the structure or any function of the body of human beings or animals; or
   4. any articles intended for use as a component of articles, specified in clauses (1), (2), or (3) not including devices or their components, parts or accessories.
   5. herbal or traditional drugs as defined in R.A. No. 9502, known as the "Universal Accessible, Cheaper and Quality Medicines Act"

F. **Drug Distributor/Importer/Exporter** refers to any establishment that imports or exports raw materials (e.g., active ingredients), and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

G. **Drug Manufacturer** refers to any establishment engaged in operations involved in the production of a drug, including propagation, processing, compounding, finishing, filling, packing, repacking, altering, ornamenting and labelling with the end in view of storage, distribution or sale of the product: provided that for the purpose of this regulation the compounding and filling of prescriptions in drugstores and hospital pharmacies shall not be considered as production operations.

H. **Drug Trader** refers to any establishment which is a registered owner of a drug product and the formulation and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or exportation in wholesale of its own drug products and importation of raw materials for the production by its contract manufacturer.

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

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

K. **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.

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

V. GENERAL GUIDELINES

A. All manufacturers, traders and distributors of drug products and raw materials shall notify the FDA of all importation/exportation of finished drug products and raw materials.

B. The notification acknowledgment shall be issued to the Marketing Authorization Holder (MAH) with valid LTO as manufacturer/trader/distributor and applicable only for the specific importation/exportation of drug products with valid CPR and to

manufacturers, traders and distributors with valid LTO that imports/exports raw materials.

C. The MAH shall submit documentary requirements to support the notification through the FDA eServices Portal System. The notification shall be submitted for every shipment.

D. Importation/Exportation of drug products and raw materials shall be channeled exclusively through the identified Bureau of Customs (BOC) port listed in Annex A. The MAH shall indicate their chosen port of entry/exit in the notification.

E. BOC ports and third party warehouses shall be inspected periodically by the FDA to ensure compliance with Good Storage Practices (GSP) and other relevant existing rules and regulations.

F. All notifications shall be filed within one month prior to the arrival/departure of the shipment to/from the Philippines.

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

H. The FDA may conduct risk-based post-marketing surveillance activities including but not limited to collection of drug product samples for testing, inspection of involved establishments/ facilities, collaboration with BOC and Law Enforcement Agencies (LEAs) and take necessary regulatory actions to violative products and establishments.

VI. SPECIFIC GUIDELINES

A. Documentary Requirements

The required details of the LTO, CPR and GMP Certificate issued by the FDA shall be encoded, and the following documentary requirements both for import and export shall be uploaded to the FDA eServices Portal System:

1. Finished Drug Product
    a. Certificate of Analysis (COA)
    b. Proforma Invoice/Commercial Invoice
    c. Packing list
2. Raw Materials
    a. Certificate of Analysis (COA)
    b. Proforma Invoice/Commercial Invoice
    c. Packing list

B. Notification Process

Guidelines on notification using eServices Portal System are provided in Annex B and the procedure on the Use of the FDA eServices Portal System for Notification is provided in Annex C.

C. Post-Notification Commitments

All manufacturers, traders and distributors with notification for importation and exportation of drug products or raw materials shall be required to input and submit the following, through the eServices Portal, as post-notification commitments:

1. Date of Arrival of the Finished Drug Products/Raw Materials
2. Bill of Lading/Airway Bill

Noncompliance on the submission of post-notification commitments shall result in regulatory action without prior notice.

VII. PENALTY CLAUSE

Violations of this Circular shall warrant the application of the sanctions and penalties under the applicable provisions of RA No. 9711 and the Implementing Rules and Regulations thereof.

Nothing in this section shall restrict the FDA, the DOH or other concerned agencies in imposing other sanctions for administrative violations of any other relevant laws or their implementing rules and regulations.

VIII. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

IX. EFFECTIVITY DATE

This Circular shall take effect fifteen (15) calendar days after publication in one (1) newspaper of general circulation and after submission to University of the Philippines, Office of the National Administrative Register (UP-ONAR).

DR. SAMUEL A. ZACATE
Director General

Keywords	Notification for Importation/Exportation, FDA eServices Portal System
Related Issuances, laws, directives from other government agencies	Republic Act No. 3720, as amended by Executive Order No. 175 and Republic Act No. 9711 and its Implementing Rules and Regulations, FDA Memorandum Circular (FMC) No. 2013-032, and, R.A. No. 11032, or the "Ease of Doing Business and Efficient Government Service Delivery Act".