FOOD AND DRUGS AUTHORITY

Date published: 2nd July 2025
FDA/ICD/GDL - 01/06
FDA Governing Board

Guideline on Processing of Import Permit and Clearance of Pharmaceutical Products

Draft written by Centre for Import and Export Control	January 2025
Draft reviewed by QMS	February 2025
Final Quality Assurance Review	25th June 2025
Approved by CEO	30th June 2025
Date of coming into effect	2nd July 2025

No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie • Greater Accra • Ghana
P. O. Box CT 2783, Accra • GPS: GA-237-7316 • (+233) 302 233200 / 235100 • fda@fda.gov.gh

Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
02/01/2019	01	Initial issue
04/06/2019	02	Insertion of sections 3.1.3, 3.1.4, 4.2 & 4.3
02/01/2020	03	Revision of 3.2.8d, 3.2.9a, 4.2 Change of document number
01/07/2022	04	Revision of clauses 3.2 and 3.2.3 Insertion of clause 4.2
02/08/2023	05	General FDA format review
03/06/2025	06	General FDA format review

Guideline on Processing of Import Permit and Clearance of Pharmaceutical Products

Table of contents

Executive Summary

The purpose of this guideline is to provide importers of pharmaceutical products with the requirements of the Food and Drugs Authority (FDA) and also provide a comprehensive procedure for bringing their activities into compliance with Part 7, section 122 of the Public Health Act 2012, Act 851. The guideline gives information, guidance and adherence to the processing of import permit products.

Detailed in this guideline are the processes and procedures involved in the application for and issuance of electronic permits as well as the inspection and release of imported pharmaceutical products.

1. Introduction (background)

Effective regulation of the importation and exportation of internationally traded products is key in ensuring the protection of the health and safety of consumers around the world. Processing of import permit for products, as carried out by the Food and Drugs Authority (FDA), typically involves permit issuance and inspection, both of which are mandated by the Public Health Act, Act 851 of 2012.

This guideline outlines the processes and procedures involved in the application for and issuance of electronic permits as well as the inspection and release of imported products.

This guideline is hereby promulgated for information, guidance and strict adherence by all concerned.

1.1 Legal Basis

In exercise of the powers conferred on the Food and Drugs Authority by Part 7, section 122 of the Public Health Act, Act 851 of 2012 and in order to ensure the safety and quality of imported products, these guidelines apply to all products imported for human or animal consumption, distribution or to be offered for sale.

Despite the above, all products to be imported shall comply with existing Ghana Standards.

1.2 Scope

The purpose of this guideline is to provide importers of products with the requirements of the Food and Drugs Authority (FDA) and also provide a comprehensive procedure for bringing their activities into compliance with the law.

2 Definitions and Abbreviations

a. FDA Food and Drugs Authority
b. eMDA Electronic Ministries Departments and Agencies
c. HS Code Harmonised System Code
d. **"Authority"** means the Food and Drugs Authority
e. **"Product"** means Pharmaceutical Products, Vaccines, other Biological Medicinal Products, Herbal Medicines, Food Supplements, Homeopathy, and Raw Materials.
f. **"Non-compliant product"** means unregistered, banned, substandard**,** falsified/ counterfeit and any other product that shall be determined by the Authority.
g. **"Reasonable quantities"** shall be determined by the Authority

h. **"Approved port"** means Tema Harbour, Kotoka International Airport and any other sea or air borders, as may be approved by the Authority from time to time.

3 Requirements

3.1 General Requirements

3.1.1. Only businesses duly licensed by the Food and Drugs Authority as an importer in accordance with Part 7, section 122 (1) of the Public Health Act, Act 851 of 2012 shall be permitted to import products.

3.1.2. Only registered products shall be permitted to be imported unless given special approval by the Authority in accordance with Part 7, sections 118 & 124 of the Public Health Act, Act 851 of 2012.

3.1.3. Products that shall require special approval by the Authority include:

- Prescription product for personal use
- Samples for Registration and promotions
- Clinical trial products/samples
- Donated products
- Emergency authorisation use

3.1.4. The product to be imported for distribution or sale shall not have a shelf life of less than sixty per cent. The drug or herbal product with a shelf life of less or equal to twenty-four months whose remaining shelf life is less than eighty per cent shall not be imported.

3.2. Applying for Import/Clearance Permit

Importers shall be required to obtain an electronic permit (eMDA document) for all imports/ consignments of product(s) prior to importation. The following information must be submitted at the "item details" column on the eMDA portal;

a. Full name (including Brand Name) of the product
b. Active Ingredients and corresponding strengths
c. Current FDA Product registration number (in full)
d. Name, address and relevant details of manufacturer (in case of raw materials)

The following information should also be provided or selected at the appropriate column during the application:

a. Appropriate HS Code for the product
b. Unit of the quantity (for e.g. ml, L, kg)
c. Postal and location address of importer
d. Phone #, Fax # and E-mail addresses of both the importer and the exporter

Application for import permit shall attract a verification fee at rates determined by the Authority and shall be dependent on the cost of the consignment (FOB amount). This verification fee is payable through any of these means: the bank, ghana.gov platform and approved points of entry prior to permit approval.

Processing of a clearance permit and accompanying invoices may take up to 24 hours or one working day after payment of requisite fees.

Response/Feedback

The applicant must monitor the status of the application on-line. Applicants are expected to go beyond the track status to approval history by opening the document.

Only approved electronic permits (eMDA) shall be used for clearance of products at the approved port of entry.

Permits issued for importation of products shall be presented to Customs only once.

In the event that goods short-land, a new permit must be processed for importation/clearance of the short-landed goods.

All incoming consignments of product(s) shall be physically inspected at the approved point of entry, including post entry applications;

a) Consignments in compliance with the Law shall be released to the importer;

b) Non-conforming consignments shall be detained under modalities determined by the FDA if they can be reasonably brought into conformance with the Law at the importer's expense; or

c) Consignments that are rejected shall either be re-exported or destroyed under the FDA's supervision, at the expense of the importer.

d) Inspection of the consignment at the approved point of entry will attract verification fee as per the Fees & Charges (LI 2386, 2019)

Physical inspection of incoming consignments of product(s) may be carried out at the importer's premises if recommended by Customs or FDA or upon request by the importer.

a) Inspection of the consignment at the importer's premises will attract a premises inspection fee as per the Fees & Charges (LI 2386, 2019)>

3.3 **Parallel importation**

For the purposes of traceability, monitoring and other regulatory actions, the Authority does not allow parallel importation of pharmaceutical products. Hence importation of products (brands) owned by another importer shall lead to the following:

a) sampling and testing of products by the Authority at the expense of the new importer.
b) full payment of the registration fee by the new importer.
b) payment of stiffer administrative fine.
c) controlled distribution of products under the monitoring of the Authority through its Market Surveillance Department (MS). An importer who imports a product that has been registered by another.

4. Sanctions and Penalties

The Authority, in accordance with Part 7, Section 129 of the Public Health Act, Act 851 of 2012, may impose a sanction/penalty for the breach of these guidelines.

Provision of false or misleading information in respect of clause 3.2 shall attract regulatory sanctions:

a) Where an applicant is found to have underdeclared the cost of a consignment (FOB amount) applicable to clause 3.2.3, he or she shall be made to pay the outstanding verification fee and 100% of the defaulted amount as administrative penalty for breach of clause 3.2.3.

Where a consignment arrives and the product(s) is not duly registered by the Authority, the following sanctions may apply:

b) Seizure and Disposal of the product.
c) Order the re-export of the product at the cost of the importer
d) Administrative fines
e) Prosecution of the importer in accordance with the provisions of the Public Health Act.

NB: Notice of Detentions "Conditional Release of consignment" shall be issued to all non-compliant products

A person who removes, alters or interferes with a detained consignment without the authority of an authorised officer commits an offence in accordance with part 7, section 136 (2) of the Public Health Act, Act 851 of 2012.