FOOD AND DRUGS AUTHORITY

GUIDELINES FOR PROCESSING OF IMPORT PERMIT AND CLEARANCE OF PHARMACEUTICAL PRODUCTS

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1.0. INTRODUCTION

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.

These guidelines outline the processes and procedures involved in the application for and issuance of electronic permits as well as the inspection and release of imported products.

These guidelines are hereby promulgated for information, guidance and strict adherence by all concerned

1.1 Scope

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.

The purpose of these guidelines 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.

1.2 Abbreviations

FDA	Food and Drugs Authority
eMDA	Electronic Ministries Departments and Agencies
HS Code	Harmonised System Code

2.0. GLOSSARY

For the purpose of these guidelines, unless the context otherwise requires;

“Authority” means the Food and Drugs Authority
“Product” means Pharmaceutical Products, Vaccines, other Biological Medicinal Products, Herbal Medicines, Food Supplements, Homeopathy, and Raw Materials.

"Non-compliant product" means unregistered, banned, substandard**,** falsified/ counterfeit and any other product that shall be determined by the Authority.

"Reasonable quantities" shall be determined by the Authority

"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.

3.0. 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, section 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

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

3.2.1. Importers shall be required to secure an eMDA permit 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, phone number and registration number of the superintendent pharmacist
e. Name, address and relevant details of manufacturer (in case of raw materials)

3.2.2. 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

3.2.3. Application for clearance permit shall attract a verification fee to be determined by the Authority and payable at the approved point of entry prior to permit approval.

3.2.4. 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.

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

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

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

3.2.8. 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)

3.2.9. 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)

4.0. SANCTIONS AND PENALTIES

4.1. 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.

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

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

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

4.3. 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.

5.0. APPENDIX

Change History

SN.	Date	Ver No.	Description of Change (section)
1.	02/01/2019	01	Initial issue
2.	04/06/2019	02	Insertion of sections 3.1.3, 3.1.4, 4.2 & 4.3
3.	02/01/2020	03	• Revision of 3.2.8d, 3.2.9a, 4.2 • Change of document number