FOOD AND DRUGS AUTHORITY

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Guideline on Processing of Export Permit and Clearance of Pharmaceutical Products

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
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Lastly, we commend the dedication of the FDA Management Team for their continuous support in strengthening regulatory frameworks to ensure public health and safety.

Executive summary

The purpose of this guideline is to provide exporters 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 export 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 pharmaceutical products intended for export.

1.0 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.

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 consignments for exportation out of the country.

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

1.1 Legal Basis

This guideline is issued pursuant to the provisions of the Public Health Act, 2012 (Act 851), specifically under Part Seven.

The legal basis for this guideline includes but is not limited to the following sections of the Public Health Act, 2012 (Act 851): Section 118, Section 122, Section and Section 129.

This guideline should be read in conjunction with the Public Health Act, Act 851, relevant Ghana Standards, and the applicable Fees and Charges Instrument (LI 2481, 2023) that governs regulatory service charges by the FDA.

1.2 Scope

In exercise of the powers conferred on the FDA by Part 7, section 118 of the Public Health Act 851, 2012, these guidelines apply to all pharmaceutical products that are to be exported from Ghana and are for the adherence by all exporters of these products.

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

The purpose of these guidelines is to provide exporters 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.

2.0 Definitions and Abbreviations

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

"Authority" means the Food and Drugs Authority

"Approved port" means Tema Harbour, Kotoka International Airport and any other sea, air and land borders, as may be approved by the Authority from time to time. Approved land borders are Aflao, Akanu, Elubo and Paga.

*"**inspection**"* is the examination of prepackaged food products in order to verify that they conform to requirements.

"***label***" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

*"**non-compliant/non-conforming product**"* means any or all of these; product is unregistered, unwholesome, banned, has too short a shelf life or does not conform to labelling rules.

"Product" means Pharmaceutical Products, Vaccines other Biological Medicinal Products, Herbal Medicines, Food Supplements, Homeopathy, and Raw Materials.

"Reasonable quantities" shall be determined by the Authority

"requirements" means the criteria relating to trade in food, covering the protection of public health, the protection of consumers and conditions of fair trade.

"unwholesome products" means products that are unfit for human consumption and include expired products or products whose parts are broken or containers are leaky etc.

3.0 Requirements

3.1 General Requirements

3.1.1 On Only businesses duly registered with the Registrar General Department shall be permitted to export products.

3.1.2 Only registered products shall be permitted to be exported unless given special approval by the Authority in accordance with Part 7, section 118 & 124 of the Public Health Act, Act 851 of 2012. Notwithstanding, products that shall require special approval by the Authority include:

- 3.1.2.1 Prescription product for personal use
- 3.1.2.2 Samples for Registration and promotions
- 3.1.2.3 Clinical trial products/samples
- 3.1.2.4 Donated products

3.1.3 The product to be exported 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 exported.

3.2 Applying for Export/Clearance Permit

3.2.1 An applicant shall, for a clearance to export prepackaged food products shall submit the following:

a. An application letter in writing addressing to:

The Chief Executive
Food and Drugs Authority
P.O. Box CT 2783
Cantonments- Accra.

b. Batch numbers, quantities per batch, pack sizes and total quantity.

3.2.2 Exporters shall be Exporters shall be required to secure an eMDA permit for all exports/ consignments of products. The following information must be submitted at the "item details" column on the eMDA portal during application;

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)

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

a. Appropriate HS Code for the product
b. Unit of the quantity (for e.g. ml, L, kg)
c. Postal and location address of exporter
d. Phone #, Fax # and E-mail addresses of both Importer and Exporter
e. 'For Export' must be indicated at the space provided for 'Purpose of Import/Export'.

3.3 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.

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

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

3.3.3 The FDA shall prior to clearance, conduct inspection of the consignment to ensure compliance with the Law.

3.3.4 Export consignments of antiretroviral, antimalarial and antibacterial drugs shall have samples picked randomly for mini lab testing for product monitoring purposes.

3.3.5 Export clearance will attract appropriate fee as per the approved Fees & Charges (LI 2386, 2019)

3.3.6 The applicant shall be held responsible for any consignment of products found to be non-compliant after the consignment has been inspected, passed and an export permit issued by the Food and Drugs Authority, or if the consignment or part of the consignment, is concealed.

3.3.7 Any consignment, batch or lot of products found to be non-compliant shall be refused an export permit. Consignments whose non-compliance(s) could be brought into conformance would be reconsidered by the Authority when duly reworked.

3.3.8 Any consignment, batch or lot of products found to be unwholesome shall be quarantined and safely disposed of under the supervision of the Food Drugs Authority.

3.3.9 The Food and Drugs Authority shall charge a fee as per the Fees & Charges (LI 2481, 2023) for the supervision of safe disposal of unwholesome consignments

4.0 Sanctions And Penalties

The Food and Drugs Authority may impose a fine for the breach of these guidelines in accordance with Section 129 of the Public Health Act 851 of 2012.