FOOD AND DRUGS AUTHORITY

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Guideline on Processing of Export Permit and Clearance of Small-scale and consolidated consignments

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Executive summary

The purpose of this guideline is to provide exporters of small-scale consolidated 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 99 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 exported foods.

1.0 Introduction (Background)

Effective regulation of the importation and exportation of internationally traded goods is key in ensuring the protection of the health and safety of consumers around the world. Clearance of FDA regulated products in small-scale or in consolidated forms, 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 and the inspection and release of all FDA regulated products earmarked for export through approved ports.

1.1 Legal Basis

This guideline is developed in pursuance of Section 99(1) and126, Parts 6 and 7 of The Public Health Act 2012, Act 851 and shall regulate all FDA products in small-scale and consolidated forms in accordance with all applicable guidelines and multilateral conventions which are currently in force:

1. Export permit and clearance of Palm Oil guidelines.
2. Guidelines for personal effects.
3. Export permit and clearance of pharmaceutical products guideline.
4. Export permit and clearance of prepackaged foods.
5. Export permit of frozen meat, fish, and other aquatic invertebrates guidelines.
6. Export permit and clearance of cosmetics, medical devices and household chemical substances guidelines.
7. Export permit and clearance of fresh fruits and vegetables guideline.
8. The Single Convention on Narcotic Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol.
9. The Convention on Psychotropic Substances of 1971 (1971 Convention) and, adopted in 1988.
10. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention).

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 Food and Drugs Authority by Parts 6 & 7, sections 99(1) and 126 of the Public Health Act, Act 851 of 2012 and in order to ensure the safety and quality of all regulated products, these guidelines apply to all small scale and consolidated shipment of FDA regulated products exported for human or animal use, distribution or to be offered for sale.

Despite the above, all FDA regulated products earmarked for export shall comply with existing Ghana Standards.

The purpose of these guidelines is to provide exporters of FDA regulated products with the requirements of the Authority for the export of small-scale and consolidated consignments and 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

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

"***Banned product***" refers to a substance which is forbidden to be a component of a product.

"Consolidated" refers to a process where a carrier or a shipping company combines several smaller shipments into one package via an approved port.

"***Controlled Substances"*** refers to a Narcotic drug, Psychotropic substance or Precursor chemical.

"cosmetic" refers to a substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes.

"Household chemical" refers to a substance or mixture of substances packaged for use in a domestic or office setting as:

a. a germicide,
b. an antiseptic,
c. a disinfectant,
d. a pesticide,
e. an insecticide,
f. a rodenticide,
g. a vermicide, or
h. a detergent;

"***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 imported cosmetics, household chemicals, medical devices;

"Narcotic drugs" refers substances listed in Schedules I and II of the 1961 Convention. The esters and ethers and the salts of esters and ethers of the narcotic drugs in Schedule I are also subject to control.

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

"Psychotropic substance" refers to those natural or synthetic substances or any natural material listed in the four Schedules of the 1971 Convention. The salts of those substances, where they exist, as well as preparations containing those substances, are subject to the same control requirements as the base substance.

"Precursor chemical" refers to those substances listed in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (1988 Convention) frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under the international control.

"***Rejected products***" means the product was deemed unfit to be distributed, sold or used in the country for reasons which may include the product being found to be fake, adulterated or contaminated;

"requirements" means the criteria relating to trade in small-scale and consolidated consignments ***and*** covering the protection of public health, the protection of consumers and conditions of fair trade; and

"***Restricted product***" means a product which is restricted to be exported out of Ghana

"Small-scale" refers to consignments determined by the Authority as small in quantity and weight.

"***Short Ship***" refers to a container that reaches the container terminal within the stack period for a certain ship but is left behind by the operator of the vessel due to many reasons.

3.0 Requirements

3.1 General Requirements

3.1.1 Only authorized exporters shall be allowed to carry out exportation of food as stipulated by Section 99(1) of the Public Health Act, 2012 (ACT 851)

3.1.2 Only businesses duly registered by the Registrar-Generals Department shall be permitted to export Authority Products.

3.1.3 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.

3.1.4 Prior approval should be obtained from the CEO's office for all biological consignments earmarked for export. Refer to the underlisted guidelines for the approval process.

1. Guidelines for application to export unregistered biological product for a named patient.
2. Guidelines for application to export registered biological product for a named patient.

3.1.5. Only an individual or a group of individuals shall be permitted to export products declared as personal effects. Companies registered with the Registrar General's Department as an exporter of FDA regulated product shall not be permitted to export personal effects.

3.1.6. Consignments containing controlled substances shall not be permitted to be exported unless given prior approval by the Authority.

3.1.7. All pharmaceuticals declared as 'for personal use' within a consolidated export shipment shall be accompanied with a prescription not exceeding 90-day duration use.

3.1.8. Small-scale and/ or consolidated palm oil consignments shall be addressed to an individual.

3.1.9. All raw materials for export shall be sourced from a registered manufacturer or wholesaler.

3.1.10. All export permits shall be valid for **ONE CALENDAR YEAR** from the date of issue.

3.2 Applying for Export Permit

3.2.1. Exporters shall be required to secure an eMDA permit for all export consignments of Authority products via the ICUMS prior to exportation. 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. FDA Product registration number (in full)
c. Name, phone number of the authorized person
d. 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:

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 All exporters are required to pay a verification fee as per the approved fee schedule (LI 2481, 2023) on all export consignments.

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 Authority products at the approved port.

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

3.3.3 If goods short-ship, a new export permit must be processed for exportation/clearance of the short-shipped goods

3.3.4 All outgoing consignments of Authority products shall be physically inspected, at the approved port of departure.

3.3.5 Consignments in compliance with the Law shall be released to be exported.

3.3.6 Consignments that are rejected shall either be returned or destroyed under the FDA's supervision, at the expense of the exporter.

3.3.7 Physical inspection of small-scale and /or consolidated consignments may be carried out at the exporter's premises if so determined by customs or FDA or on request by the exporter;

3.3.8 Inspection of the consignment at the exporter's premises will attract premises inspection fee as per the FDA approved fee schedule (LI 2481, 2023).

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.