FOOD AND DRUGS AUTHORITY

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Guideline on Processing of Export Permit and Clearance of Cosmetics, Medical Devices and Household Chemical Substances

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Executive summary

The purpose of this guideline is to provide exporters of Cosmetics, Medical Devices and Household Chemical Substances 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 118 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 cosmetics, medical devices, household chemical substances.

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.

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 exported products.

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 Food and Drugs Authority (FDA) by Part 7, section 118 of the Public Health Act 851, 2012, these guidelines apply to all cosmetics, household chemicals, medical devices that are to be exported from Ghana and are for adherence by all exporters of these products. Despite the above, all cosmetics, household chemicals, medical devices to be exported shall comply with existing Ghana Standards.

The purpose of these guidelines is to regulate and monitor the export of cosmetics, household chemicals, medical devices so as to ensure their safety and quality 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>

"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;

"medical device" refers instrument, apparatus, implement, a medical equipment, machine, contrivance, implant, in vitro reagent or any other similar or related article, including a component, part or an accessory which is:

a. Recognised in the official natural formulary or pharmacopoeia or a supplement to them, or
b. Intended for use in the diagnosis of a disease or any other condition, or in the cure, mitigation, treatment or prevention of disease in humans and animals, or
c. Intended to affect the structure or a function of the body of the human being or other animal and which does not achieve any of its principal intended purposes through chemical action within the body of the human being or any other animal and which is not dependent on being metabolised for the achievement of any of its principal intended purposes;

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

"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.

"***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; and

"requirements" means the criteria relating to trade in cosmetics, household chemicals, medical devices, covering the protection of public health, the protection of consumers and conditions of fair trade.

3.0 Requirements

3.1 General Requirements

3.1.1 Only businesses duly registered by the Registrar-General's Department shall be permitted to export cosmetics, household chemicals, medical devices.

3.1.2 The cosmetics, household chemicals, medical devices to be exported must be registered with the Food and Drugs Authority in accordance with Part 7, section 118 & 124 of the Public Health Act, Act 851 of 2012.

3.1.3 A person shall not be permitted to export cosmetics, household chemicals, medical devices unless issued with an export permit by the Food and Drugs Authority in accordance with these guidelines for each consignment of cosmetics, household chemicals, medical devices.

3.2 Applying for Export/Clearance Permit

3.2.1 An applicant shall, for a clearance to export cosmetics, household chemicals, medical devices 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 required to secure an electronic permit (eMDA) for all exports/ consignments of cosmetics, household chemicals, medical devices. The following information must be submitted at the "item details" column on the eMDA portal;

- Full name (including Brand Name) of the product
- FDA Product registration number (in full)
- Name and contact number of Authorized Person

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

- Appropriate HS Code for the product
- Unit of the quantity (ml, L, kg etc)

- Full Address of Exporter (including location address)
- Phone #, Fax # and E-mail addresses of both Importer and Exporter
- 'For Export' must be indicated at the 'Purpose of Import/Export' Column.

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 cosmetics, household chemicals, medical devices 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 to the Law.

3.3.4 Export clearance will attract appropriate fee as per the FDA approved fee schedule (LI 2481, 2023).

3.3.5 The applicant shall be held responsible for any consignment of cosmetics, household chemicals, medical devices found to be non-compliant after the consignment has been inspected, passed and a certificate of free sale issued by the authority, or if the consignment or part of the consignment, is concealed.

3.3.6 Any products found to be non-compliant shall be refused a certificate of free sale. Consignments whose non-compliance(s) could be brought into conformance would be reconsidered by the Authority when duly reworked.

3.3.7 Any products found to be unwholesome shall be quarantined and safely disposed of under the supervision of the Food and Drugs Authority.

3.3.8 The Food and Drugs Authority shall charge a fee as stated in the Food and Drugs Authority fee schedule for the supervision of safe disposal of unwholesome consignments (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.