FOOD AND DRUGS AUTHORITY

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

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02/01/2019	01	Initial issue
02/01/2020	02	• Insertion of sections 3.1.3, 3.1.4, 4.2 & 4.3; • Revision of clauses 3.2.3.4., 3.2.7.1., 3.2.8.1. Change of document number and logo
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02/08/2023	04	General FDA format review
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Executive Summary

The purpose of this guideline is to provide importers 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 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 Cosmetics, Medical Devices and Household Chemical Substances.

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 Parts 6 & 7, section 122 of the Public Health Act, Act 851 of 2012 and in order to ensure the safety and quality of imported cosmetics, household chemicals and medical devices, these guidelines apply to all cosmetics, household chemicals and medical devices imported for human or animal use, distribution or to be offered for sale.

Despite the above, all imported cosmetics, household chemicals, medical devices to be imported shall comply with existing Ghana Standards.

1.2 Scope

The purpose of these guidelines is to provide importers of cosmetics, household chemicals and medical devices 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

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 imported 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 and medical devices***, covering the protection of public health, the protection of consumers and conditions of fair trade.

3. Requirements

1.1. 3.1 General Requirements

1.1.1. 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.

1.1.2. 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.

1.1.3. The cosmetics, household chemicals, or medical devices to be imported 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.

1.1.4. However, if by chance the consignment arrives and it's not duly registered, a pseudo registration number (temporary code) shall be issued to the importer for permit application and clearance of the consignment from the port.

1.1.5. Such consignments shall be cleared under detention followed by registration of the product immediately the consignment leaves the port.

1.2. Applying for Import Permit

1.2.1. Importers shall be required to secure an eMDA permit for all imports/consignments of cosmetics, household chemicals, or medical devices via the GCNet 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. 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)

1.2.2. 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

1.2.3. Application for import permit shall attract a verification fee to be determined by the Authority and shall be dependent on the declared FOB on the invoice accompanying the consignment (s). This verification fee is payable at the approved point of entry prior to permit approval.

1.2.4. 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.

1.2.5. Only approved electronic permits (eMDA) shall be used for clearance of cosmetics, household chemicals, medical devices at the port of entry.

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

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

1.2.8. All incoming consignments of cosmetics, household chemicals, medical devices shall be physically inspected, at the port of entry, including post entry applications;

1.2.8.1. Consignments in compliance with the Law shall be released to the importer;

1.2.8.2. 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

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

1.2.8.4. Inspection of the consignment at the port of entry will attract verification fee as per the FDA approved fee schedule (LI 2386, 2019).

1.2.9. Physical inspection of incoming consignments of cosmetics, household chemicals, medical devices may be carried out at the importer's premises if so determined by Customs or the FDA or on request by the importer;

1.2.9.1. Inspection of the consignment at the importer's premises will attract premises inspection fee as per the FDA approved fee schedule (LI 2386, 2019).

1.2.10. The authority in the execution of its legal mandate as entrenched in Part 7, section 135 of the Public Health Act 2012, Act 851, may detain and subject consignments of cosmetics and condoms (medical device) to laboratory testing for monitoring and surveillance of hydroquinone with its derivatives and sub-standard condoms respectively. The importer is therefore expected to wait and cooperate with FDA to be satisfied with the laboratory results before the consignment may be released.

1.2.10.1. On account where a test is positive (e.g. hydroquinone tested positive or condoms found to be sub-standard), the whole consignment shall be disposed of at the cost of the importer following FDA approved fee schedule (LI 2386, 2019).

3.3. Parallel importation

3.3.1 For the purposes of traceability, monitoring and other regulatory actions, the Authority does not allow parallel importation of cosmetics, medical devices and

household chemical substances. 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

4.1 The Food and Drugs Authority may impose a fine for the breach of these guidelines in accordance with Part 7, Section 129 of the Public Health Act, Act 851 of 2012.

4.2 Where an applicant is found to have altered the FOB applicable to clause 3.2.3, he or she shall be made to pay the required verification fee in addition to 100% of the defaulted amount as administrative fine for breach of clause 3.2.3.

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

4.3.1 **"Clearing under detention"** followed by registration of the product immediately the consignment leaves the port.
4.3.2 Seizure and Disposal of the product.
4.3.3 Order the re-export of the product at the cost of the importer
4.3.4 Administrative fines
4.3.5 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

4.4 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.