FOOD AND DRUGS AUTHORITY

7th August 2023
FDA/OPS/GDL - 01/03

Guideline on Safe Disposal of Unwholesome Products

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This guideline replaces 'Guideline for Safe Disposal of Unwholesome Products' (FDA/DRI/DMS/GL-SDP/2013/03)

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
20/03/2013	01	Initial issue of Guideline.
15/03/2019	02	Adoption of new FDA Logo.
07/08/2023	03	To cover all FDA- regulated products. Inclusion of definition for substandard and falsified products.

Guideline on Safe Disposal of Unwholesome Products

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Executive summary

The Food and Drugs Authority (FDA) is established under the Public Health Act, 2012, Act 851 to ensure public health and safety. The authority is also responsible under section 132 of the Public Health Act, 2012, to supervise the safe disposal of unwholesome regulated products including Substandard/Falsified products.

In exercise of the powers conferred on the Authority by Part Seven, Section 148 of the Public Health Act, 2012, (Act 851), this guideline applies to the safe disposal of regulated products that are unwholesome for both human and animal consumption.

1.0 Introduction (background)

This guideline has been developed to provide guidance to all stakeholders handling drugs, medical devices, cosmetics, and household chemical substances (hereafter referred to as products) to ensure safe disposal of unwholesome products and prevent its re-entry into the supply chain.

It also provides a comprehensive procedure for bringing the activities of manufacturers, processors, producers, wholesalers, retailers, importers and exporters, having unwholesome products, into compliance with Part Seven, Section 132 subsection 2 & 3 of Public Health Act, 2012, (Act 851).

These guidelines are hereby made for information, guidance, and strict compliance by all concerned.

1.1 Legal Basis

The Authority is also responsible under section 132 of the Public Health Act, 2012, to supervise the safe disposal of unwholesome regulated products including Substandard/ Falsified products.

1.2 Scope

In pursuance of **Sections 132 of the Public Health Act 2012, Act 851**, these Guidelines are hereby made to provide for the proper handling, treatment and disposal of unwholesome products to protect human health and the environment from potential hazards.

2.0 Definitions and Abbreviations

a) **Non-Compliant Product:** Means any product that does not meet regulatory requirements or when consumed/used can be injurious to the health of the consumer; including Substandard/Falsified (SF) products.
b) **Disposal:** Means the destruction of unwholesome product beyond retrieval.
c) "**Substandard"** these are authorized medical products that fail to meet either their quality standards or specifications, or both.
d) **"Falsified"** medical products that deliberately/ fraudulently misrepresent their identity, composition, or source.

Abbreviations

a) MAH – Market Authorization Holder
b) SF - Substandard and Falsified products
c) SOP – Standard Operating Procedure

3.0 Requirements

3.1 General Requirements

3.1.1 No person shall dispose of any unwholesome product without permission and supervision from the Food and Drugs Authority (FDA).
3.1.2 Approval of application and safe disposal of any unwholesome product shall be sought from the FDA.
3.1.3 The applicant shall pay a prescribed fee for destruction as specified in the fe e schedule.
3.1.4 The applicant shall arrange with the appropriate Waste Management Agency with the approval of the FDA to assist in the destruction and be responsible for conveyance of the unwholesome products to the site of destruction.
3.1.5 Where necessary, representatives from the Environmental Protection Agency, Customs Division of Ghana Revenue Authority, Audit Service and the Ghana Police Service shall be present as witnesses.
3.1.6 Management of unwholesome product shall include;
a) maintaining a register for unwholesome products
b) keeping separately unwholesome products especially products that fall under controlled drugs and any other hazardous product.
c) Keeping unwholesome products into different categories by dosage forms (e.g. solids, liquids, etc.)
d) Unwholesome products should be clearly labelled to avoid its unintended use.

3.2 Specific Requirements

3.2.1 All applications for destruction of unwholesome products shall be made to

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3.2.2 The letter shall be accompanied by a filled application form and the list of products in both ***hard*** and ***soft copy (excel format)*** with the following details:

A) Drugs, Cosmetic Medical Devices and Household Chemicals

- **a)** Product description
- **b)** Quantities
- **c)** Unit cost
- **d)** Total commercial values and
- **e)** Reason (s) for which the products are declared unwholesome.

Batch (applicable to recalled SF products)

B) Food

- **a)** Product description
- **b)** Quantities (Kg)
- **c)** Quantities (MT)
- **d)** Reason (s) for which the products are declared unwholesome.
- **e)** Batch (applicable to recalled SF products)

3.2.3 The applicant shall also pay a non-refundable fee (find information on Approved Fee Schedule on the FDA website – https://fdaghana.gov.gh/images/stories/pdfs/Quick%20links/FDA%20FEES%20SCHEDULE.pdf)

3.2.4 The Authority shall, upon receipt of the request for disposal, appoint a regulatory officer to verify and authenticate the information submitted in relation to the consignment to be disposed. If after verification, the submitted list is varied by addition of other products, the applicant shall be made to pay an additional fee as required. The Authority shall upon the receipt of a request for safe disposal, conduct a verification exercise. If a variation (addition of other products) is realized after the exercise, the applicant shall be made to pay an additional fee as required.

3.2.5 The applicant shall arrange and agree with the FDA on a convenient date on which the destruction can be undertaken. The applicant and the FDA shall agree on a date for the destruction activity.

3.2.6 The Authority shall after completion of the disposal exercise issue a certificateof destruction of the products. The Authority after completion of the destruction activity, shall issue of safe disposal certificate.

4.0 Penalties

4.1 Any person who contravenes or fails to comply with any provision of these Regulations or who directly or indirectly aids another person in committing an offence under these Regulations commits an offence under the Act.

4.2 Any person convicted of an offence under these regulations shall be liable to a fine in accordance with Part Seven, Section 129 of the Public Health Act, 2012,(Act 851).