FOOD AND DRUGS AUTHORITY

GUIDELINES FOR SAFE DISPOSAL OF UNWHOLESOME PRODUCTS

Document No.	**:**	FDA/MCH/MSD/GL-SDP/2019/03
Date of First Adoption	**:**	1st November, 2019
Date of Issue	**:**	1st November 2019
Version No.	**:**	00

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1 INTRODUCTION

The Food and Drugs Authority (FDA) is established under 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.

These guidelines have 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 it's 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.

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1.1 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 regulated products so as to protect human health and the environment from potential hazards.

2 GLOSSARY

a) **Authority:** Means the Food and Drugs Authority
b) **Destruction:** Means the safe disposal of any unwholesome products beyond retrieval.
c) **Product:** means any locally-manufactured or imported medical devices, cosmetics, household chemicals, investigational products as defined under the Public Health Act, 2012 Act 851.
d) **SF:** Means Substandard and falsified products.
e) **Unwholesome Product:** Means any product that does not meet regulatory requirement or when consumed/used can be injurious to health of the consumer; Including Substandard / Falsified (SF) products.

3 REQUIREMENTS

3.1 General Requirements

3.1.1 No person shall dispose off 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 fee schedule.
3.1.4 The applicant shall arrange with the appropriate Waste Management Agency to assist in the destruction and also 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 Excise and Preventive Services (CEPS), 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 product
b) keeping separately unwholesome products especially products that fall under controlled drugs and any other hazardous products
c) keeping unwholesome products into different categories by dosage forms (e.g. solids, liquids etc)
d) unwholesome products should be clearly labeled to avoid its unintended use.

3.2 Specific Requirements

3.2.1 All applications for destruction of unwholesome products shall be made to the FDA office through a letter addressed to

THE CHIEF EXECUTIVE FOOD AND DRUGS AUTHORITY
P.O.BOX CT 2783
CANTONMENTS – ACCRA

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

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

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

4 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).