



FOOD AND DRUGS AUTHORITY

GUIDELINES FOR COMPLAINTS

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1. INTRODUCTION

1.1. BACKGROUND

The Food and Drugs Authority (FDA) is the National Regulatory Agency with the responsibility of regulating the import, export, manufacture, distribution, sale and use of all food, drugs, herbal medicines, medical devices, cosmetics, household chemical substances, tobacco and tobacco products and clinical trial oversight in Ghana. The FDA is established under section 80 of the Public Health Act, 2012, Act 851 with object to provide and enforce standards for the sale of all regulated products.

The FDA has established a quality management system to measure customer feedback through complaints in order to help improve its services of ensuring public health and safety. The system helps to identify customer dissatisfaction and also aids the Authority to identify areas where changes can be made in order to improve customer satisfaction.

This document has been established to provide the public and stakeholders with guidance on complaint management process regarding the quality of services provided as well as the quality, safety, efficacy/effectiveness, handling/storage, manufacture etc. of FDA-regulated products.

The general public is encouraged to give feedback on the various regulatory functions relating to the services provided by the Authority, regulatory infractions by persons/institutions and product defects identified on the market (both physical and online).

1.2. SCOPE

This Guideline has been developed to provide guidance on complaint relating to:

- a) Regulatory irregularities relating to the services/activities provided by the Authority

- 30 b) Regulatory infractions of importation, export, manufacturing, distribution, sale
31 and use of FDA regulated products
32 c) Defective FDA regulated products
33

34 2. GLOSSARY

35 **Complaint:** This is defined as an expression of dissatisfaction about a service provided
36 by the FDA or the identity, quality, safety, efficacy/effectiveness, handling/storage,
37 manufacturing etc. of an FDA-regulated product or illegal activities concerning FDA
38 regulated products.

39 **Service-Related Complaints:** These are complaints relating to dissatisfied services
40 provided by FDA such as:

- 41 • Mistakes that could result in a misunderstanding or omission
- 42 • Undue delays
- 43 • FDA officer behaviour
- 44 • Poor or misleading information
- 45 • Other service-related issues

46 **Non-service Related complaints:** These are complaints relating to suspected
47 defective FDA- regulated products or Regulatory infractions such as:

- 48 • Unregistered products
- 49 • Substandard or falsified products
- 50 • Expired products
- 51 • Illegal importation, exportation, manufacturing, distribution, sale and use of FDA
52 regulated products

53 Suspected or confirmed defects may be classified into three categories, according to
54 the risk posed to general public and/or consumers.

- 55 • Critical quality defects are potentially life threatening or could pose a serious risk
56 to consumers, including patient or animal health.

- 57 • Major quality defects are those which could cause illness or mistreatment but are
58 not critical
- 59 • Minor quality defects are those which are unlikely to pose a risk to consumers,
60 including patients and or animal health.

61

62 **3. REQUIREMENTS**

63 **3.1. GENERAL**

- 64 1. Complaints may be lodged at FDA through letters, e-mail, telephone, social media,
65 SMS, or in person.
- 66 2. Written complaints (letters or email) should be addressed to:
- 67 **THE CHIEF EXECUTIVE OFFICER**
68 **FOOD AND DRUGS AUTHORITY**
69 **POST OFFICE BOX CT 2783**
70 **CANTONMENTS**
71 **ACCRA, GHANA**
- 72 3. Complaint forms are available on the FDA website, which can be completed and
73 submitted at the FDA offices or emailed to fda@fdaghana.gov.gh
- 74 4. Complaints may be lodged at the FDA Head Office - Accra, Tema Port Office, or
75 any of the Regional offices (addresses and contacts are provided in Appendix I).
- 76 5. Complainants are assured that information provided in the complaint form will be
77 treated as confidential information.
- 78 6. Complaint submission, investigation and response shall not result in any
79 discriminatory actions against the complainant. All complaints will be treated fairly
80 including those submitted anonymously.

81

82 **3.2. COMPLAINT MANAGEMENT**

- 83 1. Complaints received formally by the Authority will receive acknowledgement within
84 10 working days and after investigation, the outcome will be communicated to the
85 complainant.

- 86 2. Generally, the timeframe for resolving complaints is dependent on the complexity of
87 the complaint. Despite the nature of the complaint, FDA will ensure that the
88 complainant is regularly updated (monthly) on the status of the investigation. The
89 final outcome of the investigation will be communicated to the complainant using the
90 most appropriate means.
- 91 3. Service-related complaints shall be resolved within two (2) months from the date of
92 receipt of the complaint.
- 93 4. Feedback to the outcome of the investigation will be based on the mode of
94 submission or the complaint, information provided during submission or as
95 appropriate.
- 96 5. The general public is assured that the FDA has defined routes and procedures to:
- 97 • Formally receive complaint through proper documentation and completion of the
98 appropriate completion form
 - 99 • Process complaint in a uniform and timely manner
 - 100 • Evaluate the content/nature of the complaint and accompanying documentation
101 and generate an outcome to provide guidance for redress
 - 102 • Effect regulatory action, and
 - 103 • Provide feedback to the complainant with a summary of the actions taken.
- 104 6. In the case that a complainant is not satisfied with the outcome of the complaint, the
105 complainant may appeal against the decision as per the **Guidelines on Appeal**
106 **Against Regulatory Decisions of the Food and Drugs Authority** which is
107 available on the FDA website.

APPENDIX 1: FDA CONTACT DETAILS

Sn.	FDA Office	Location Address	Postal Address	Telephone / Others
1	Head office / Laboratory Services	Number 17 Indian Ocean Street Nelson Mandela Avenue South Legon Commercial Area, Shiashie	Post Office Box CT 2783 Cantonments Accra-Ghana	Telephone: +233 (0) 302 235 100 +233 (0) 302 233 200 Hotline: +233 (0) 299 802 932 +233 (0) 299 802 933 Fax: +233 (0) 302 229 794 +233 (0) 302 225 502 E-mail: fda@fdaghana.gov.gh
REGIONAL OFFICES				
2	Koforidua Office	Hsp. Rd. Opp. Assemblies of God Church	Post Office Box KF 2431, Koforidua	Telephone: +233 (0) 342 020 580/1 Fax: +233 (0) 342 021 250
3	Sunyani Office	Opp. Regional Hospital (behind Healthway Diagnostic Services)	PMB-FDA, Sunyani	Telephone: +233 (0) 350 028 791 Fax: +233 (0) 352 028 790
4	Ho Office	Opp. GWCL (same building with Cool FM)	Private Mail Bag. Ho	Telephone: +233 (0) 362 026 659 Fax: +233 (0) 362 028 411
5	Kumasi Office	Regional Coordinating Council (RCC) next to Electoral Commission's Office, Danyame, Kumasi.	Post Office Box ST 402, Kumasi	Telephone: +233 (0) 322 036 070 +233 (0) 279 960 126 +233 (0) 541 072 778/6
6	Wa Office	Controller Block Ministries	Post Office Box 291, Wa.	Telephone: +233 (0) 392 020 111 Fax: +233 (0) 390 020 001
7	Bolgatanga Office	Regional Administration Building, Bolgatanga	Post Office Box 612, Bolgatanga	Tel/Fax: +233 (0) 382 023 727

Sn.	FDA Office	Location Address	Postal Address	Telephone / Others
8	Tamale Office	Regional Administration Building, Tamale.	Post Office Box TL 1763, Tamale.	Tel: +233 (0) 372 024 935
9	Cape Coast Office	UCC Credit Union Building Adjacent Cedecon Building, Junction	Post Office Box CC 1373, Cape Coast	Telephone: +233 (0) 332 090 110 +233 (0) 548 802 541 +233 (0) 254 839 521 +233 (0) 504 422 905 Tel/Fax: +233 (0) 332 132 300
10	Takoradi Office	SSNIT Building Near Central Police Station	Post Office Box MC 2129, Takoradi	Telephone: +233 (0) 312 027 558 Fax: +233 (0) 312 027 558
IMPORTS AND EXPORT CONTROL SERVICES				
11	Tema Harbour Office			Telephone: +233 (0) 303 2113410/8 Fax: +233 (0) 302 213 418
12	Kotoka Int. Airport Office	Aviation Premises		Telephone: +233 (0) 302 784 653
13	Takoradi Harbour Office	Nick TC Scan Area	Post Office Box TD 213, Takoradi	
14	Aflao Office	CEPS Premises (Check Point)		Tel/Fax: +233 (0) 362 530 846
15	Elubo Office	CEPs Border Area, Elubo		Tel/Fax: +233 (0) 345 225 38