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
b) Regulatory infractions of importation, export, manufacturing, distribution, sale and use of FDA regulated products

c) Defective FDA regulated products

2. GLOSSARY

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

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

- Mistakes that could result in a misunderstanding or omission
- Undue delays
- FDA officer behaviour
- Poor or misleading information
- Other service-related issues

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

- Unregistered products
- Substandard or falsified products
- Expired products
- Illegal importation, exportation, manufacturing, distribution, sale and use of FDA regulated products

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

- Critical quality defects are potentially life threatening or could pose a serious risk to consumers, including patient or animal health.
Major quality defects are those which could cause illness or mistreatment but are not critical.

Minor quality defects are those which are unlikely to pose a risk to consumers, including patients and or animal health.

3. REQUIREMENTS

3.1. GENERAL

1. Complaints may be lodged at FDA through letters, e-mail, telephone, social media, SMS, or in person.

2. Written complaints (letters or email) should be addressed to:

   THE CHIEF EXECUTIVE OFFICER
   FOOD AND DRUGS AUTHORITY
   POST OFFICE BOX CT 2783
   CANTONMENTS
   ACCRA, GHANA

3. Complaint forms are available on the FDA website, which can be completed and submitted at the FDA offices or emailed to fda@fdaghana.gov.gh

4. Complaints may be lodged at the FDA Head Office - Accra, Tema Port Office, or any of the Regional offices (addresses and contacts are provided in Appendix I).

5. Complainants are assured that information provided in the complaint form will be treated as confidential information.

6. Complaint submission, investigation and response shall not result in any discriminatory actions against the complainant. All complaints will be treated fairly including those submitted anonymously.

3.2. COMPLAINT MANAGEMENT

1. Complaints received formally by the Authority will receive acknowledgement within 10 working days and after investigation, the outcome will be communicated to the complainant.
2. Generally, the timeframe for resolving complaints is dependent on the complexity of the complaint. Despite the nature of the complaint, FDA will ensure that the complainant is regularly updated (monthly) on the status of the investigation. The final outcome of the investigation will be communicated to the complainant using the most appropriate means.

3. Service-related complaints shall be resolved within two (2) months from the date of receipt of the complaint.

4. Feedback to the outcome of the investigation will be based on the mode of submission or the complaint, information provided during submission or as appropriate.

5. The general public is assured that the FDA has defined routes and procedures to:
   - Formally receive compliant through proper documentation and completion of the appropriate completion form
   - Process compliant in a uniform and timely manner
   - Evaluate the content/nature of the compliant and accompanying documentation and generate an outcome to provide guidance for redress
   - Effect regulatory action, and
   - Provide feedback to the complainant with a summary of the actions taken.

6. In the case that a complainant is not satisfied with the outcome of the complaint, the complainant may appeal against the decision as per the Guidelines on Appeal Against Regulatory Decisions of the Food and Drugs Authority which is available on the FDA website.
## APPENDIX 1: FDA CONTACT DETAILS

<table>
<thead>
<tr>
<th>Sn.</th>
<th>FDA Office</th>
<th>Location Address</th>
<th>Postal Address</th>
<th>Telephone / Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Head office / Laboratory Services</td>
<td>Number 17 Indian Ocean Street Nelson Mandela Avenue South Legon Commercial Area, Shiashie</td>
<td>Post Office Box CT 2783 Cantonments Accra-Ghana</td>
<td>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: <a href="mailto:fda@fdaghana.gov.gh">fda@fdaghana.gov.gh</a></td>
</tr>
<tr>
<td>2</td>
<td>Koforidua Office</td>
<td>Hsp. Rd. Opp. Assemblies of God Church</td>
<td>Post Office Box KF 2431, Koforidua</td>
<td>Telephone: +233 (0) 342 020 580/1 Fax:+233 (0) 342 021 250</td>
</tr>
<tr>
<td>3</td>
<td>Sunyani Office</td>
<td>Opp. Regional Hospital (behind Healthway Diagnostic Services)</td>
<td>PMB-FDA, Sunyani</td>
<td>Telephone: +233 (0) 350 028 791 Fax: +233 (0) 352 028 790</td>
</tr>
<tr>
<td>4</td>
<td>Ho Office</td>
<td>Opp. GWCL (same building with Cool FM)</td>
<td>Private Mail Bag. Ho</td>
<td>Telephone: +233 (0) 362 026 659 Fax: +233 (0) 362 028 411</td>
</tr>
<tr>
<td>5</td>
<td>Kumasi Office</td>
<td>Regional Coordinating Council (RCC) next to Electoral Commission’s Office, Danyame, Kumasi.</td>
<td>Post Office Box ST 402, Kumasi</td>
<td>Telephone: +233 (0) 322 036 070 +233 (0) 279 960 126 +233 (0) 541 072 778/6</td>
</tr>
<tr>
<td>6</td>
<td>Wa Office</td>
<td>Controller Block Ministries</td>
<td>Post Office Box 291, Wa.</td>
<td>Telephone: +233 (0) 392 020 111 Fax: +233 (0) 390 020 001</td>
</tr>
<tr>
<td>7</td>
<td>Bolatanga Office</td>
<td>Regional Administration Building, Bolatanga</td>
<td>Post Office Box 612, Bolatanga</td>
<td>Tel/Fax: +233 (0) 382 023 727</td>
</tr>
</tbody>
</table>

**REGIONAL OFFICES**
<table>
<thead>
<tr>
<th>Sn.</th>
<th>FDA Office</th>
<th>Location Address</th>
<th>Postal Address</th>
<th>Telephone / Others</th>
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<tbody>
<tr>
<td>8</td>
<td>Tamale Office</td>
<td>Regional Administration Building, Tamale.</td>
<td>Post Office Box TL 1763, Tamale.</td>
<td>Tel: +233 (0) 372 024 935</td>
</tr>
<tr>
<td>9</td>
<td>Cape Coast Office</td>
<td>UCC Credit Union Building Adjacent Cedecon Building, Junction</td>
<td>Post Office Box CC 1373, Cape Coast</td>
<td>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</td>
</tr>
<tr>
<td>10</td>
<td>Takoradi Office</td>
<td>SSNIT Building Near Central Police Station</td>
<td>Post Office Box MC 2129, Takoradi</td>
<td>Telephone: +233 (0) 312 027 558 Fax: +233 (0) 312 027 558</td>
</tr>
<tr>
<td>11</td>
<td>Tema Harbour Office</td>
<td></td>
<td></td>
<td>Telephone: +233 (0) 303 2113410/8 Fax: +233 (0) 302 213 418</td>
</tr>
<tr>
<td>12</td>
<td>Kotoka Int. Airport Office</td>
<td>Aviation Premises</td>
<td></td>
<td>Telephone: +233 (0) 302 784 653</td>
</tr>
<tr>
<td>13</td>
<td>Takoradi Harbour Office</td>
<td>Nick TC Scan Area</td>
<td>Post Office Box TD 213, Takoradi</td>
<td>Tel/Fax: +233 (0) 362 530 846</td>
</tr>
<tr>
<td>14</td>
<td>Aflao Office</td>
<td>CEPS Premises (Check Point)</td>
<td></td>
<td>Tel/Fax: +233 (0) 345 225 38</td>
</tr>
<tr>
<td>15</td>
<td>Elubo Office</td>
<td>CEPs Bordeer Area, Elubo</td>
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