FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

Client Service Delivery Charter

Food and Drugs Authority

TABLE OF CONTENTS

ACKNOWLEDGEMENT

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The Monitoring and Evaluation Division and the various Departments that provided information for finalisation of this service delivery charter are hereby acknowledged for their contributions. Last but not the least the Governing Board of the FDA is acknowledged for the review and approval of this service delivery charter for the FDA.

Yvonne Nkrumah (Mrs)
DCE CORPORATE SERVICES

FORWARD

The role of the FDA in Government of Ghana's commitment to improve the business environment cannot be overemphasised. Through effective, efficient and transparent regulatory service delivery the FDA supports Government's industrialisation agenda in programmes such as the Planting for Food and Jobs, 1D1F, National Entrepreneurship Innovation Programme (NEIP), Private Sector Development and the African Continental Free Trade Agreement (AfCFTA) .

The 2020 client service delivery charter which supersedes the first edition, has been revised to align with the 2020-25 FDA Strategy Compass and captures the new services on offer; it also captures issues of anticorruption which is currently being driven by the National Anticorruption Action Plan (NACAP). This edition will boost the confidence of our clients and strengthen our relationship with them.

Timely provision of quality service remains our heartbeat in our quest for excellence as we pursue our mandate of protecting public health and safety. Daily our Officers live out our core values of integrity, accountability and teamwork to give the best to our clients, consumers and other stakeholders.

Without the cooperation of our clients, consumers and other stakeholders we will not be able to achieve our mandate. It is important that clients and consumers adhere to the relevant regulations while their needs are being attended to by FDA officers. Our highly valued clients, you are encouraged to read this charter to appraise yourself with your rights and responsibilities. Your suggestions are welcome as they enable us to serve you better.

Delese A.A. Darko (Mrs)
CHIEF EXECUTIVE OFFICER

GLOSSARY

AFCFTA	-	African Continental Free Trade Agreement
CIF	-	Cost, Insurance, and Freight
CEO	-	Chief Executive Officer
DFID	-	Department for International Development
FDA	-	Food and Drugs Authority
GHS	-	Ghana Health Service
GII	-	Ghana Integrity Initiative
NACAP	-	National Anti-Corruption Action Plan
NEIP	-	National Entrepreneurship Innovation Program
1D1F	-	One District One Factory
PEF	-	Private Enterprises Federation
SDC	-	Service Delivery Charter
TCA	-	Technical Advisory Committees
USD	-	United States Dollar

1. INTRODUCTION

This document specifies the services and service standards clients should expect from the Ghana Food and Drugs Authority, as well as the procedure to follow if the agreed services are not rendered efficiently. The Service Delivery Charter (SDC), is in line with the broader Public Service Policies of providing quality services to the Public in Ghana, and preventing and fighting administrative corruption.

2. PURPOSE OF THE CHARTER

This Charter shall:

a. Broadly state the services offered by the FDA.
b. Outline the general service standards that underpin the services that the FDA offers.
c. Confirm the Code of Conduct that is applicable to all public officials.
d. Provide contact details of all FDA Offices across the country.
e. Provide contact details for reporting complaints and corruption related complaints in the provision of the services of the FDA.

3. PROFILE

The Food and Drugs Authority (FDA) is the national regulatory body in Ghana mandated by Parts 6, 7 and 8 of the Public Health Act, 2012 (Act 851) to assure the safety, quality and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant local and international standards to protect the health and safety of the people in Ghana.

The FDA is an agency of the Ministry of Health. It has a Governing Board whose constitution is defined by Part 7 of the Public Health Act 2012, Act 851. The Chief Executive Officer reports to the Governing Board and is responsible for the strategic direction and daily operational management of the organisation. The FDA has five (5) Technical Advisory Committees for safety of medicines, safety of vaccines and biological products, medical devices, clinical trials and nutrition in line with best international practice. The Authority is ISO 9001:2015 certified.

The FDA's critical role in the national health delivery system in Ghana cannot be overemphasized as the medical products it regulates are essential in the diagnosis, treatment and/or management of diseases. The importance of food in our lives is summed up by this Hippocrates quote: *"Let food be thy medicine and medicine be thy*

food." The FDA ensures that the consumption of food does not contribute to the disease burden through sound food control practices. The effectiveness and efficiency of the FDA in the execution of its mandate is, therefore, critical to the health of the Nation.

The FDA has a quality control laboratory at Tema and two in Accra; the lab at the Head Office is accredited to ISO 17025:2017 for forty-four (44) tests. The FDA has offices at Tema and Takoradi Seaports, Kotoka International Airport, and borders at Aflao, Akanu, Kpoglo and Ho Borders in Volta Region; Elubo in Western Region; efficiency of the FDA in the execution of its mandate is, therefore, critical to the health of the Nation.

The FDA has offices in ten (10) out of the sixteen (16) regions across Ghana. Currently, Tamale Regional Office in the Savannah Region has responsibility for the Northern and North East Regions; Sunyani Office in the Bono Region has responsibility for the Ahafo and Bono East Regions; Ho Regional Office in the Volta Region has responsibility for the Oti Region; and the Takoradi Regional Office in the Western Region has responsibility for the Western North Region. The FDA collaborates with all relevant Ministries, Departments and Agencies as well as the various Metropolitan, Municipal and District Assemblies across the country.

4. LEGAL MANDATE

The Food and Drugs Board was established by the Food and Drugs Law 1992 (PNDCL 305B) and was amended by the Food and Drugs (Amendment) Act 523, 1996, to provide for the fortification of salt to alleviate nutritional deficiencies and to bring the provisions of the law in conformity with the 1992 Constitution of the Republic of Ghana.

In 2012 the Food and Drugs (Amendment) Act 523, 1996 was revised and integrated as Parts 6, 7 & 8 of the Public Health Act 2012, Act 851 making explicit provisions for tobacco control and clinical trial regulation and the renaming of the organisation as the Food and Drugs Authority. This therefore forms the primary legislation defining FDAs mandate. In pursuing its mandate of protecting public health and safety, the FDA utilises relevant national and international standards as well as other local legislation relevant to the regulation of products under its purview. These include but are not limited to:

a. General Labelling Rules (Food, Drugs and Other Goods), 1992 (LI 1451).
b. Ghana Breastfeeding Promotion Regulations, 2000 (LI 1667).
c. Tobacco Control of Regulations 2016 (LI 2247).

d. International Pharmacopeia
e. US Pharmacopeia
f. British Pharmacopeia
g. Codex Standards
h. Ghana Standards

5. VISION

To protect the health and safety of people in Ghana and be a global centre of excellence for food and medicinal product regulation.

6. MISSION

The FDA exists to assure the safety, quality and efficacy of human and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant standards to protect public health.

7. OBJECTIVE

The object of the FDA is to provide and enforce standards for the sale of food, herbal medicinal products, cosmetics, drugs, medical devices and household chemical substances.

8. FUNCTIONS

The functions of the FDA as spelt out by the Public Health Act, 2012 (ACT 851) are as follows:

i. Enforce standards for human (allopathic and herbal) and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control and use of tobacco products.
ii. Register food, human (allopathic and herbal) and veterinary drugs, biological products, cosmetics, household chemical substances and tobacco products.
iii. License facilities for manufacture and storage, and vehicles for the transportation of FDA regulated products.
iv. Issue food hygiene permit for food service establishments, meat shops, abattoirs and slaughter slabs.
v. Issue import and export permits for FDA regulated products.
vi. Free-sale certificate for the export of FDA regulated products.
vii. Carryout market surveillance of FDA registered products.
viii. Monitor adverse effects in the use of FDA regulated products.
ix. Approve and monitor advertisement of FDA regulated products.
x. Investigate consumer complaints for FDA regulated products.

i. Enforce standards for human (allopathic and herbal) and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances, clinical trials, and the control and use of tobacco products.
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viii. Monitor adverse effects in the use of FDA regulated products.
ix. Approve and monitor advertisement of FDA regulated products.
x. Investigate consumer complaints for FDA regulated products.
xi. Provide industrial support services to manufacturers of FDA regulated products.
xii. Provide clients services to companies and individuals.
xiii. Monitor FDA regulated products at all ports of entry.
xiv. Approve the initiation and conduct of clinical trials.
xv. Test all FDA regulated products to ensure conformance to all relevant standards.
xvi. Educate the public on safe handling and use of FDA regulated products.
xvii. Monitor through the District Assemblies and any other agency of State' compliance with the provisions of Parts 6, 7 and 8 of Act 851.
xiii. Develop effective Regulations for the implementation of Parts 6, 7 and 8 of Act 851.
xix. Advise the Minister on measures to protect public health and safety.

9. ACCESSIBILTY OF SERVICES

The Service is available to all members of the public on weekdays except public holidays. Working hours are 8h00 to 16h30.

10. CORE VALUES

The organisational culture at the FDA is characterised by:

- Integrity
- Teamwork
- Accountability

11. SERVICES AND SERVICE STANDARDS

SERVICE	PROCESSING TIME*
Import and Export Control	
Permit Issuance for all FDA regulated products	
Import permit	Within 1 day
Export permit	Within 1 week
Clearance of FDA regulated products	
Imported products	Within 1 day
Issuance of certificate of free sale and manufacture	
Palm oil	Within 5 weeks
Other FDA regulated products	Within 2 weeks
Listing of importers of all FDA regulated products	Within 3 weeks
Product Registration	
Market authorisation of allopathic, veterinary & biologicalproducts.	
New applications - foreign	Within 6 months
New applications – local	Within 3 months
Renewal applications	Within 2 months
Food supplements	
Registration	Within 3 months
Re-registration	Within 2 months
Supplementary/Additional data	Within 4 months
Market authorisation for priority medicines (Vaccines, HIV, TB, Malaria, medicines for neglected tropical diseases, medicines for reproductive health and diseases with unmet needs)	
New application	Within 3 months
Renewal application	Within 2 months
Supplementary/Additional data	Within 2 months

Market authorisation for products reviewed under reliance pathway.	
New application	Within 3 months
Renewal application	Within 2 months
Market authorization for Herbal Medicines & Food Supplements	
New applications - foreign	Within 6 months
New applications - local	Within 3 months
Renewal applications	Within 1 month
Authorisation of Variations for Medical Products	
Major	Within 6 months
Minor	Within 4 months
Notification	Within 1 month
Market authorisation for Food Products	
New application (local and foreign)	Within 30 working days
Renewal (local and foreign)	Within 20 working days
Premium service (for low-risk products)	
New application	Within 15 working days
Renewal	Within 10 working days
NB: Timelines for premium services exclude bulk application.	
Market authorisation for Cosmetics & Household Chemicals	
New applications - low risk- foreign	Within 2 months
New applications - high risk - foreign	Within 6 months
New applications - low risk - local	Within 1 month
New applications - high risk - local	Within 5 months
Renewal applications	Within 3 weeks
Market authorisation for Medical Devices	
Fresh application for Class I – IV Medical Devices (foreign and Local)	Within 6 months

Renewal application for Class I - IV Medical Devices (Foreign and local)	Within 3 months
Minor variation	Within 3 months
Major variation	Within 6 months
Premises Registration	
Issuance of manufacturing license for local medical products manufacturing facility (human, veterinary, herbal, cosmetics, household chemicals & medical devices).	
New application	Within 4 weeks
Renewal application	Within 3 weeks
Issuance of GMP certificate for foreign medical productsmanufacturing facility (human, veterinary, herbal, cosmetics, household chemicals & medical devices).	
New application	Within 3 months
Renewal application	Within 2 months
Issuance of storage facility license for medical products manufacture (human, veterinary, herbal, cosmetics, householdchemicals & medical devices).	
New application	Within 1 month
Renewal application	Within 1 month
Issuance of manufacturing license for local food product(including animal feed & animal products)	
New applications	Within 4 weeks
Renewal application	Within 3 weeks
Issuance of GMP certificate for foreign food manufacturingfacilities (including animal feed & animal products)	
New applications	Within 3 months
Renewal application	Within 2 months

Issuance of storage/packhouse facility license for food product(including animal feed, agro produce & animal products)	
New applications	Within 4 weeks
Renewal application	Within 3 weeks
Issuance of food hygiene permit for food service establishments.	
New applications	Within 1 month
Renewal application	Within 3 weeks
Issuance of licence for Meat Shops	
New applications	Within 1 month
Renewal applications	Within 1 month
Clinical Trial Authorisation	
Issuance of clinical trial authorisation	
Processing of clinical trial applications (routine pathway)	Within 60 days
Processing of clinical trial applications (reliance pathway)	Within 30 days
Processing of import permits for investigational products	Within 10 days
Processing of quarterly progress and safety reports	Within 15 days
Notification of receipt of electronic submissions includingSAE reports	Within 5 days
Communicating GCP inspection findings	Within 21 days
Processing of applications for protocol amendment	Within 30 days
Processing of final clinical trial reports	Within 30 days
Tobacco, Tobacco Products & Substance of Abuse	
Market Authorisation of Tobacco and Tobacco Products	
New applications	Within 3 months
Renewal applications	Within 1 month
Variation applications	Within 3 months
Issuance of permits for narcotic drugs & psychotropic substances	Within 1 week

Advertisements	
Approval of advertisement for all FDA regulated products	
New application - regular	Within 1 month
Renewal application - regular	Within 2 weeks
Premium service	Within 5 days
Other Services	
Product name search	Within 4 weeks
Product label evaluation	Within 4 weeks
Request for product information	Within 1 week
Scientific advice meeting	Within 2 weeks
Request for analysis of FDA regulated products	Within 6 weeks
Accelerated shelf-life studies	Within 8 months

NOTE: these timelines are subject to fulfilment of all requirements. It does not Include time taken by applicant to address queries and non-compliances. The FDA as part of upholding our core value on integrity we commit to keeping the above timelines.

The procedures, (checklists) for accessing the services in this clause 12 are located under Guidelines and Forms on the FDA website www.fdaghana.gov.gh.

12. FEES AND CHARGES

The fees and charges are dependent on the service being rendered and may be subject to changes bi-annually. The current fees and charges for our services are listed in the Approved Fees and Schedule on the FDA website, www.fdaghana.gov.gh.

13. RIGHT TO CLIENTS

a. The right to privacy and confidentiality
b. The right to lodge a complaint
c. The right to be provided with information
d. The right to access services, facilities and information in a manner which meets the needs of the clients.
e. The right to appeal against FDA regulatory decisions in line with the provisions in the Public Health Act 2012, Act 851 and FDA guideline for appeal against regulatory decisions on the FDA website www.fdaghana.gov.gh.

14. WHAT WE EXPECT FROM CLIENTS AND THE PEOPLE OF GHANA

a. Compliance to all relevant requirements, guidelines and regulations for all applications. All these documents are available together with the requisite forms are located under Guidelines and Forms on the FDA website www.fdaghana.gov.gh.
b. Information provided in applications and communications to the FDA must be true and accurate.
c. Patronise the nearest FDA offices in Accra, Tema and all our regional offices for enquiries, information and guidance. Details on location of all our offices can be found at the contact section of the FDA website.
d. Honour invitations to participate in workshops and stakeholder engagements.
e. Provide information on non-compliant FDA regulated products on the market using the contact details provided in section 16.1.
f. Treat FDA staff with respect and courtesy.
g. Be honest and truthful in your engagement with FDA staff.
h. Respond to requests for information precisely and on time.
i. Provide feedback (complaints, compliments and suggestion) in respect of our services using the suggestion box and during our satisfaction surveys to help us improve our services.
j. Observe all rules and procedures, and co-operate with us while we serve with you.

15. RESPONSIBILITIES OF STAFF

a. Treat all clients with respect and courtesy.
b. Give equal opportunity to our clients.
c. Provide exemplary services as required by this service delivery charter.
d. Promptly respond to all service enquiries.
e. Available and accessible to clients and consumers.
f. Uphold FDA core values of integrity, teamwork and accountability in all our dealing with our clients and consumers.
g. Resolve complaints efficiently and promptly.

16. FEEDBACK – COMMENDATIONS, SUGGESTIONS AND COMPLAINTS

We strive to deliver exceptional customer service. Should you have any problem concerning the quality of our services; we encourage you to provide feedback. Whether you have a request for action, a compliment, or suggestion, we will like to hear from you.

a. We encourage members of the public to lodge complaints and make suggestions, comments and compliments through the physical address, the postal address or telephone numbers identified below.
b. We guarantee confidentiality and privacy regarding the complainants'

identity and the subject of complaint.

c. We encourage complainants to identify themselves adequately to enable us to handle their issues adequately and efficiently without unnecessary bottlenecks that may be caused by anonymity.

16.1 For Complaints and Compliments

Chief Executive Officer
P. O. Box CT 2783
Cantonments - Accra
Contact telephone numbers – 0302 235100 / 225502
Email - complaints@fda.gov.gh

16.2 To Report Fraud and Corruption

FDA has a zero tolerance for corruption. We take any corruption complaints extremely seriously, and thus provide below separate contact details for corruption related complaints.

Chief Executive Officer
P. O. Box CT 2783
Cantonments - Accra
Contact telephone numbers – 0302 2229261
Email - fda@fda.gov.gh

16.3 Internal Complaint Handling Mechanism

This Service Delivery Charter is published to provide information about the standards we aim for in providing our services. You are therefore invited to comment on whether our standards are delivering the level of service you require and whether or not we deal effectively with your enquiries. Your comments are extremely useful to us in determining how we need to develop and improve our services and for updating the contents of this Charter.

Complaints may be made through any of the following means:

a. Pick and complete a complaint form at the FDA reception desk.
b. Call the appropriate phone numbers above.
c. Send an email to the appropriate email address above.
d. Write a letter to the CEO using the address above

We will acknowledge receipt of your complaints within twenty-four (24) hours of receipt, provide update on its status within three (3) working days, and communicate the resolution of the complaint as stated in our previous correspondence to you on the issue.

16.4 The Issues That Are Covered By This Procedure

This procedure is for use by client to make complaints and comments relating to quality of service they received at the FDA, for example:

a. Complaints about issues such as delays, mistakes, non-availability of information, availability of quality of information, rude behaviour.
b. Instances where the service you received was below standards indicated in this service charter.
c. Complaints under the Persons with Disability Act, 2009 (Act 715) relating to access to our premises, etc.

Complaints in relation to staff members will be dealt with in accordance with the FDA's Grievance Policy and Procedures. It does not cover complaints about other activities of the FDA where there are existing statutory mechanisms in place to deal with such complaints/appeals e.g. conviction for criminal offences.

16.5 External Complaint Handling Mechanism

Where client is still dissatisfied with the internal complaint resolution, the client can contact the Commission on Human Rights and Administrative Justice (The Public Services Ombudsman) or any other appropriate Review/Appellate body. As a final resort, Client may appeal to:

The New Charter Office
c/o Office of the President
Ministry of Public Sector Reform
Accra
Telephone: 0302 672333 / 684086 / 671359

16.6 Measuring and Evaluating Performance

We will put appropriate mechanisms in place to measure and evaluate performance against the commitments in our Charter, which we will keep under review in order to continuously improve our service. We will report on our performance in our Annual Report. We will use a range of measurements/evaluation tools to measure our performance including:

- Satisfaction surveys
- Suggestion box

While it is our aim to deliver a high-quality service to our clients, we recognise that situations may arise in which a client may be dissatisfied with the quality of service provided. The Client Service Complaints Procedure outlined above provides a transparent mechanism to have and grievances addressed.

16.7 Other

Kindly use our feedback systems to provide useful information on your service experience. We welcome feedback on this service delivery charter.

Chief Executive Officer
P. O. Box CT 2783
Cantonments - Accra
Contact telephone numbers – 0302 235100 / 225502
Email - info@fda.gov.gh

17. WHERE TO FIND THE ORGANIZATION

Physical Location

No. 17 Indian Ocean Street, Nelson Mandela Avenue, Accra
Office Address: P.O. Box M44, Accra
Email: info@fda.gov.gh
Telephone: (+233) 302 - 233200 / 235100
Hotlines: 0551112223 / 0551112224 / 0551112225
Toll free: 0800151000
Website: https://fdaghana.gov.gh/index.php

FDA Social Media Pages

Facebook: fdaghana
Twitter: fdaghana
Instagram: fdaghana_
Youtube: fdaghana
Google Business: fdaghana
LinkedIn: Food and Drugs Authority Ghana

17.1 Location of Offices

Head Office

No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie
P.O Box CT 2783
Accra. GPS: GA-237-7316
Telephone: 03022 35100

17.2 Regional Offices

The contacts and location of our regional offices are stated in **Annex 1.**

18. PERIODIC MONITORING AND REVIEW OF CHARTER

This SDC will be reviewed every two years.

19. ANNEXES

Annex 1: Contacts and location of our regional offices

Upper West Region
P.O.Box 291, Wa
Location: Controller Block, Ministries, Wa
Telephone: 0392 020 111
Mobile: 0244 470 413
GPS: XW-0021-9492

Bono Region
PMB, Sunyani
Location: House No. 61A Nkwabeng Extension, Sunyani
Near St. Mary's School, Adj. Goode Goode Spot.
Telephone : 233352028791 / 0265 062 697

Upper East
P.O.Box 612, Bolgatanga
Location: Regional Administration Building, Bolgatanga
Telephone: 0382 023 727
Mobile: 0247 717 744 / 0500 233 377
GPS: UB-0034-4017

Volta Region
PMB, Ho
Location Opposite Ghana Water Works (Same building with Kuul FM)
Telephone: 0362 026 659
Mobile: 0247 978 956/ 0244 339 632
GPS: VH-0016-3748

Eastern Region
P.O.Box KF 2431, Koforidua
Location: Regional Hospital Road, Opposite Assemblies of God Church
Mobile: 0277 705 752
GPS: EN-011-2579

Northern Region
P.O.Box TL 1763, Tamale
Location: Regional Administration Building
Telephone: 0367 202 4935 / 0208 120 901
Mobile: 0544 349 911
GPS: NT-0066-3381

Ashanti Region
P.O.Box ST 402, Kumasi
LOCATION: Ashanti Regional Coordinating Council, Next to Electoral Commision
TEL: 0322036027/70
MOBILE: 0507187420-2
GPS: AK-133-7324

Central Region
P.O.Box 1373, Cape Coast
Location: UCC Credit Union Building, adjacent CEDECOM
Telphone: 0332090110
Mobile: 0245 839 521 / 0504 422 905
GPS: CC-097-0402

Western Region
P.O.Box MC 2129, Takoradi
Location: SSNIT Building
Mobile: 0544338829
GPS: WS-247-9180