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REQUIREMENTS FOR REGULATED PRODUCTS

OUTLINE

Mandate of FDA

Food Product Registration

Food Facility License

Site Verification

Food Service Establishment

Drugs, Veterinary and Herbal Medicines

Cosmetics, Household Chemicals,

Medical Devices

Facility Licensing and Import Permit

Advertisements

FDA CORE MANDATE

A National Regulatory Body

- Food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols.

Ensure Public Health Safety

- Registration
- Inspection
- Market Surveillances
- Intelligence
- Advertisement
- Testing

MANUFACTURING FACILITY LICENSE REQUIREMENTS - FOOD

- Cover Letter
- Completed Application Forms
- Copy of Business Registration Certificate
- Heath Certificate of Food Handlers
- Layout of Facility

Application Fees:

- Cottage Industry - GH¢ 100.00
- Small Scale Industry - GH¢ 200.00
- Medium Scale Industry- GH¢ 300.00
- Large Scale Industry - GH¢ 700.00

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COLD & DRY STORAGE FACILITY LICENSE REQUIREMENTS

- Cover Letter
- Completed Application Forms
- Copy of Business Registration Certificate
- Layout of Facility

Application Fees:

- Small Scale - GH¢ 240.00
- Medium Scale - GH¢ 500.00
- Large Scale - GH¢ 800.00

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SITE VERIFICATIONS - FOOD

$10,500.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from outside Africa

$8,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from Africa

$6,000.00 when importing Canned Tomato Paste, Fish and Meat Products and Infant Formula from West Africa and for all products imported from Nigeria

NB: FACILITY LICENSING IS A PREREQUISITE TO PRODUCT REGISTRATION

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PRE- PACKAGED FOOD PRODUCT REGISTRATION REQUIREMENT (Imported & Local)

- Cover Letter
- Completed Application Forms
- Copy of Business Registration Certificate
- Certificate of Analysis of all Products and its Variants
- Samples as Per Schedule
- (Option) Mock Samples with Model Label

Local

Cottage Industry	- GH¢ 300.00
•Small Scale Industry	- GH¢ 600.00
•Medium Scale Industry	- GH¢ 900.00
•Large Scale Industry	- GH¢ 1500.00

Imported

- 1 to 30 Products - GH¢ 750.00
- •31 to 500 products - GH¢ 600.00
- •501 to 1000 products - GH¢ 450.00
- •More than 1000 products - GH¢ 300.00

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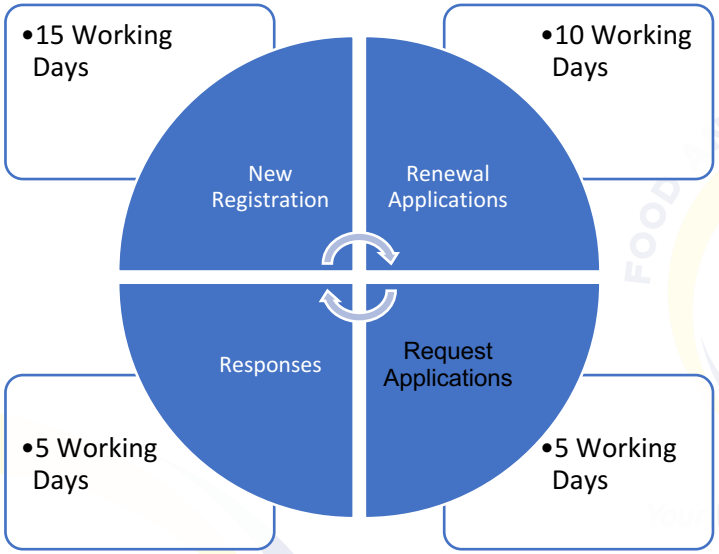
PREMIUM SERVICES TIMELINES FOR FOOD REGISTRATION



All Applications for Premium, 3 times Charges

Exceptions

1.High-Risk Products (Frozen meat/ Fish, Infant Foods, Novel Foods, Canned Fish/Meat/Tomato, Egg and Egg Products)
- Products that require payment of site verification
- Bulk Food Product Applications

FOOD SERVICE ESTABLISHMENTS

Cover Letter

Completed Application Forms

Copy of Business Registration Certificate

Copy of Food Handlers Certificates for Cooks and Waiters

Application Fee:

Small Industry
-GH¢120

Medium Industry
-GH¢240

Large Industry
-GH¢600

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STORAGE AND MANUFACTURING FACILITIES - DRUGS

- Cover Letter
- Completed Application Forms
- Copy of Business Registration Certificate

Cottage	-GH¢ 200 per year
Small Scale	-GH¢ 300 per year
Medium Scale	-GH¢ 400 per year
Large Scale	-GH¢ 500 per year

Pharmaceutical

Small Scale per year	-GH¢ 1000
Large Scale per year	-GH¢ 3000

Cottage	-GH¢120
Small Scale	-GH¢240
Medium Scale	-GH¢500
Large Scale	-GH¢800

STORAGE AND MANUFACTURING FACILITIES – COSMETICS/ MDCHC

- Cover Letter
- Completed Application Forms
- Copy of Business Registration Certificate

Cottage	-GH¢ 50 per year
Small Scale	-GH¢ 100 per year
Medium Scale	-GH¢ 200 per year
Large Scale	-GH¢ 400 per year

Cottage	-GH¢120
Small Scale	-GH¢240
Medium Scale	-GH¢500
Large Scale	-GH¢800

SITE VERIFICATIONS – OTHER THAN FOOD

$10,500.00 when importing from outside Africa

$8,000.00 when importing from Africa

$6,000.00 when importing from West Africa

NB: FACILITY LICENSING IS A PREREQUISITE TO PRODUCT REGISTRATION

IMPORT PERMIT

- Cover Letter
- Completed Application Forms

Registration Requirements for Drugs

Allopathic

- Cover Letter
- Completed Dossier on 2 CD's
- Samples - Sample Schedule
- Fee:
  - Imported - $1,200
  - New Chemical - $1800
  - Orphan Drugs - $300
- Local – GHC5,000
- Veterinary - $ 600

Herbal

- Cover Letter
- Completed Application Forms
- Certificate of Analysis
- Stability Study Report*
- Free Sale Certificate*
- Samples
- Fee:
  - Imported - $1,200
  - Local – GHC500

Supplements

- Cover Letter
- Completed Application Forms
- Certificate of Analysis
- Stability Study Reports*
- Free Sale Certificate*
- Samples
- Fee
  - Imported - $ 600
  - Local – GHC500
  - Veterinary - $600

Biologics

- Cover Letter
- Completed Dossier on 2 CD's
- Samples
- Fee:
  - Imported - $1800
  - Local – GHC 2,500

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COSMETICS, HOUSEHOLD CHEMICALS

- Cover Letter
- Completed Application Forms
- Certificate of Analysis, Free Sale Certificate, Manufacturing License
- Copy of Business Registration Certificate
- Samples as Per Schedule

Local

Cottage Industry	-GH¢ 300
Small Scale Industry	-GH¢ 600
Medium Scale Industry	-GH¢ 900
Large Scale Industry	-GH¢ 1,500

Imported

1-30 Products	-$177
31-500 Products	-$111
501-1000 Products	-$72
> 1000 Products	-$21

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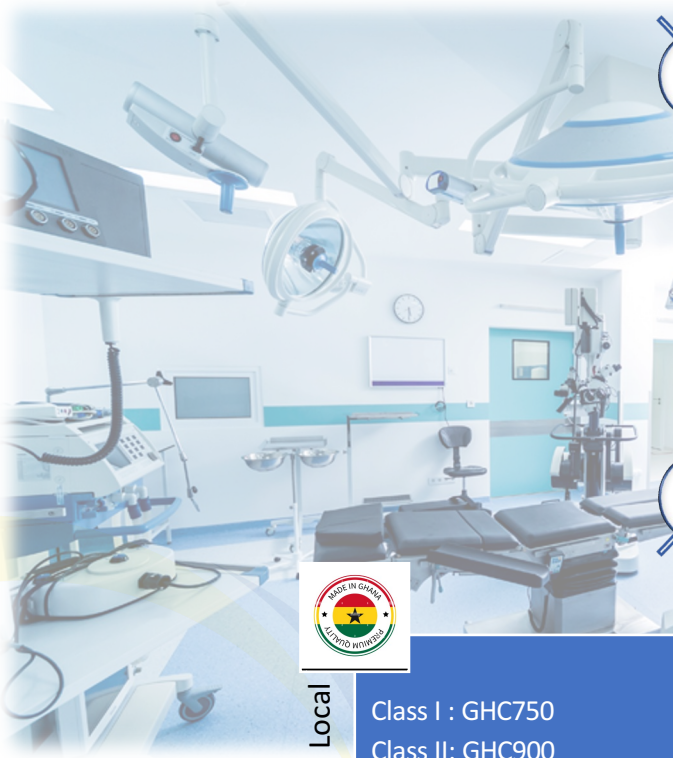
MEDICAL DEVICES REQUIREMENTS



- Cover Letter
- Completed Application Forms
- Certificate of Analysis, Free Sale Certificate, Manufacturing License
- Copy of Business Registration Certificate
- Samples as Per Schedule

Local

Class I : GHC750
Class II: GHC900
Class III: GHC1,050
Class IV: GHC1,200

Imported

Class I : $180.
Class II: $300.
Class III: $480.
Class IV: $600.

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ADVERTISEMENTS

- Cover Letter
- Completed Application Forms
- Advert Script/ Artwork/ Storyboard
- Copy of Product Registration Certificate
- Application Fee: Per Media/language/Script/Product
  - Regular -GH¢800
  - Express -GH¢2,000

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THANK YOU

ANY QUESTIONS
PLEASE?

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FOOD AND DRUGS AUTHORITY

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COMMUNICATIONS & PUBLIC EDUC. DEPT

OUTLINE

- Introduction to the FDA
- Strategic focus
- Our operations
- Accreditations
- Collaborations & Affiliations
- Managing a pandemic
- Our initiatives
- How to stay connected with us

Introduction to the Food and Drugs Authority

The FDA was established in **August 1997** as the Food and Drugs Board (FDB) under the Food and Drugs Law, 1992 (PNDCL 305B).

PNDCL 305B in 2012 was integrated into the **Public Health ACT 851, 2012 and** with the name Food and Drugs Authority.

The Food and Drugs Authority is mandated by Parts 6, 7, 8 & 9 of the Public Health Act 2012, Act 851 to *protect public health and safety*.

Strategic focus…

Vision is to protect the health and safety of people in Ghana and be a global Centre of Excellence for food and medical products regulation.

Mission

The FDA exists to ensure 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 of tobacco products through the enforcement of relevant standards to protect public health.

Our core values

Integrity

Accountability

Teamwork

How we are funded…

We are funded both by Government of Ghana and internally generated funds (IGF).

IGF is generated via

- Fees for regulatory services such as products registration, licensing of facilities etc.
- Administrative fines for non-compliance to regulations.
- Percentage of free on board (FOB) cost of imported products.

Our regulatory activities…

The products we regulate:

Allopathic medicines

Herbal medicines

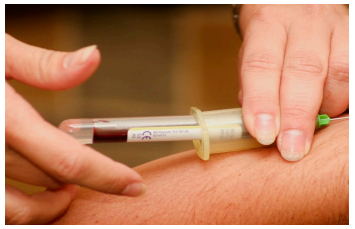
Food

Medical devices

Household chemicals

Cosmetics

Tobacco & Tobacco products



Blood & blood products

Vaccines

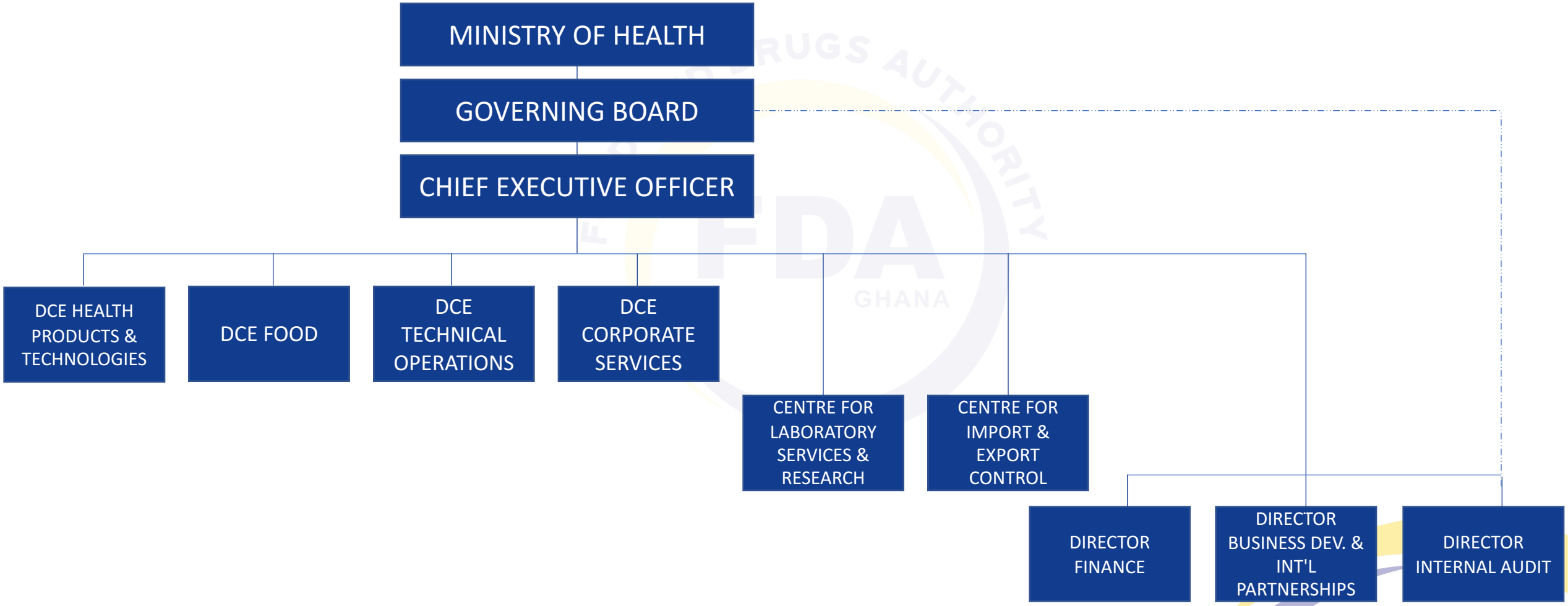
Some of our key activities include:

- **Registration** of FDA-regulated products.
- **License** manufacturing, storage, and distribution facilities.
- **Market surveillance** of FDA-regulated products**.**
- Authorisation and monitoring **clinical trials**.
- **Safety monitoring** of FDA-regulated products.
- Provide **industrial support** to *local manufacturers*.
- **Enforce standards** for FDA-regulated products as well as **tobacco control** regulations.
- **Advertisement** approval and monitoring

Operational Offices…

FDA has offices in 12 Regions in the country

Our organogram…



Centre for Laboratory Services & Research

Our state of the art laboratory ascertains the s
quality and efficacy of regulated products.

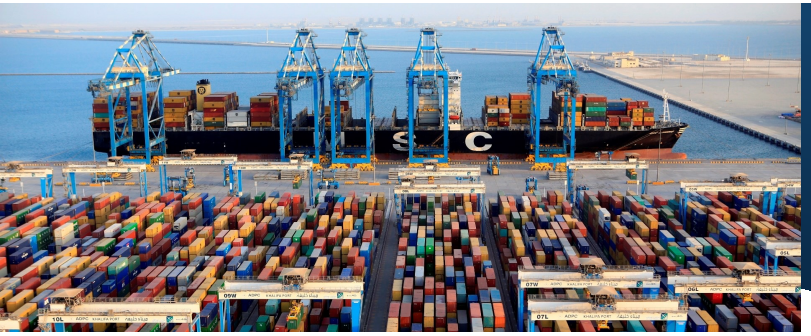
OVERVIEW OF THE FDA LAB:

The Centre has **6 testing Laboratories and a Quality Assurance Office.** The testing laboratories include:

- ❖ Drug Physiochemical
- ❖ Food Physiochemical
- ❖ Pharmaceutical Microbiology
- ❖ Food Microbiology
- ❖ Cosmetic/ Household Chemical Substances
- ❖ Medical Devices

We offer commercial testing services

Centre for Import and Export Control



The Centre for Import and Export Control (CIEC) comprises [illegible] **airport (KIA)**, **2 seaports**, and **12 border posts**.

CORE ACTIVITIES:

- ❖ Issuance of permits
- ❖ Inspection and clearance of imported products
- ❖ Import data analytics
- ❖ Sampling and testing of high-risk products
- ❖ Inspection of export cargo
- ❖ Inspection of customs bonded warehouses

No Registration
No Importation

ISO Accreditation …

Our administrative, operational and quality control [illegible] accredited to ISO standards.

- Our administrative and operational procedures for FDA offices in Greater Accra, Volta, and Ashanti Regions are certified to **ISO 9001:2015** since 2017.
- Our Quality Assurance function maintains ISO/IEC 17025:2017 for testing and calibration laboratories and ISO 9001:2015 for quality management systems. Our drug laboratory is WHO-prequalified.
- We have the largest scope of accredited tests under a single roof in Africa.

Regional Centre of Regulatory Excellence (RCORE)

The FDA has been designated by AUDA-NEPAD and [illegible] RCORE since 2014 for Clinical Trials, Medicine Evaluation and Registration and Medicines Safety

RCORE ACTIVITIES :

- ❖ Annual 30-day fellowship course
  - Clinical trial authorisation
  - GCP inspections
  - Adverse events and safety monitoring
  - Regulatory attachment
- ❖ Capacity building in medicines dossier assessment

More than 60 regulators in Sub-Saharan Africa trained

International Collaborations & Affiliations

The FDA has been actively involved in regulatory activities on the Continent and beyond.

COLLABORATIONS & AFFILIATIONS

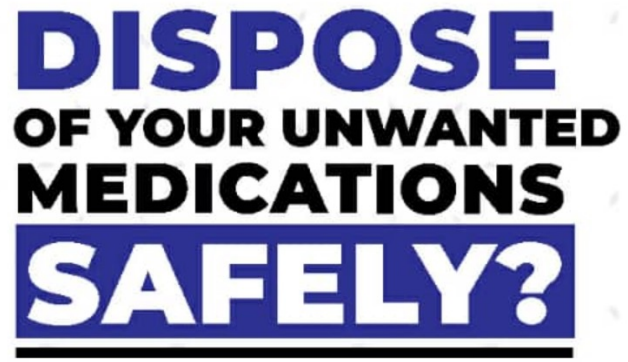
- Member of African Vaccine Regulatory Forum (AVAREF)
- Non-EU member of European Medicines Agency (EMA) Good Clinical Practice (GCP) Inspectors' Working Group.
- Lead coordinating country for West Africa Medicines Regulatory Harmonization (WA-MRH) Project.
- Participate in the WAHO Joint Medicine Evaluation Harmonization Process
- Africa Medicines Regulation Harmonisation
- Member of the WHO Programme for International Drug Monitoring
- WHO/ CIOMS Committee on Vaccine Safety
- UK MHRA
- Paul Ehrlich Institute

Initiatives…

1. **Take Back Unwanted Medicines (TBUM)** is an FDA project to promote safe disposal of unused and expired medical products.

2. **Progressive License Scheme (PLS)** this aims to support small business units to improve on the safety, quality and wholesomeness of their products.

3. **Promotion of Made-In-Ghana goods** in large supermarket chains to boost their patronage.



Social media…

Like, Follow, Share …

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@Food and Drugs Authority Ghana

@Food and Drugs Authority Ghana

@fdaghana

@fdaghana_

ABARAKA

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PROGRESSIVE LICENSING SCHEME AND BUY GHANA, LOVE GHANA CAMPAIGN

Presented by

RESEARCH AND PUBLICATION UNIT

OUTLINE

- Introduction
- Objectives
- FDA's support to MSME's
- Impact
- Challenges encountered

Introduction

- Ghana's private sector currently consists of manufacturing, services, and agricultural industries, and more than 85% of these are Micro, Small and Medium Enterprises (MSMEs) contributing about 70% of our GDP.

- To support this vital sector, the FDA has implemented targeted initiatives to formalize, empower, and promote these enterprises in food and cosmetics manufacturing.

Progressive Licensing Scheme (PLS)

- **What is the PLS?**
  A regulatory framework by the FDA to support Micro/Cottage and Small-Scale Enterprises (MSEs) in the food (excluding water), cosmetics, and household chemical industries by providing support in meeting regulatory requirements with ease and convenience without compromising on quality and safety standards.
- **Why PLS?**
  Helps MSEs overcome challenges in product registration
  Provides gradual regulatory compliance
  Enhances public health, product safety, and traceability
- **Who is Eligible?**
  Businesses with 1–5 production staff directly involved

- **Three-Stage Licensing System**

  Pink (Level 1): Initial Compliance
  Yellow (Level 2): Intermediate Compliance
  Green (Level 3): Full Regulatory Compliance

Key Components of the Progressive Licensing Scheme

- **Phased Approach to Compliance**: The idea is to help small businesses improve their operations step by step, with each level reflecting greater adherence to safety and quality standards.
- **Entry-Level Licensing**: At the first stage, businesses are granted an initial license that allows them to legally operate under minimal regulatory requirements.
- **Capacity Building and Training**: This support includes guidance on GMP, quality control, packaging, labeling, and product testing.
- **Monitoring and Mentorship**: Businesses under the PLS are regularly monitored and mentored by the FDA.
- **Graduation to Full Licensing**: Once a business has successfully met all the requirements laid out for each stage of the scheme, it "graduates" to fully compliance.
- **Product and Facility Upgrades**: The scheme encourages businesses to upgrade their facilities and processes over time. By spreading out the financial and logistical burdens of meeting full compliance, it makes it easier for businesses to invest in better equipment, training for staff, and improvements to their production lines, to ensure they meet FDA standards in the long run.

The Buy Ghana, Love Ghana Campaign

The Buy Ghana, Love Ghana campaign was launched in 2020 as part of the implementation of the Progressive Licensing Scheme. As the initial activity, the FDA encouraged some A-rated supermarkets and malls to allocate special stands for the promotion of Made in Ghana products.

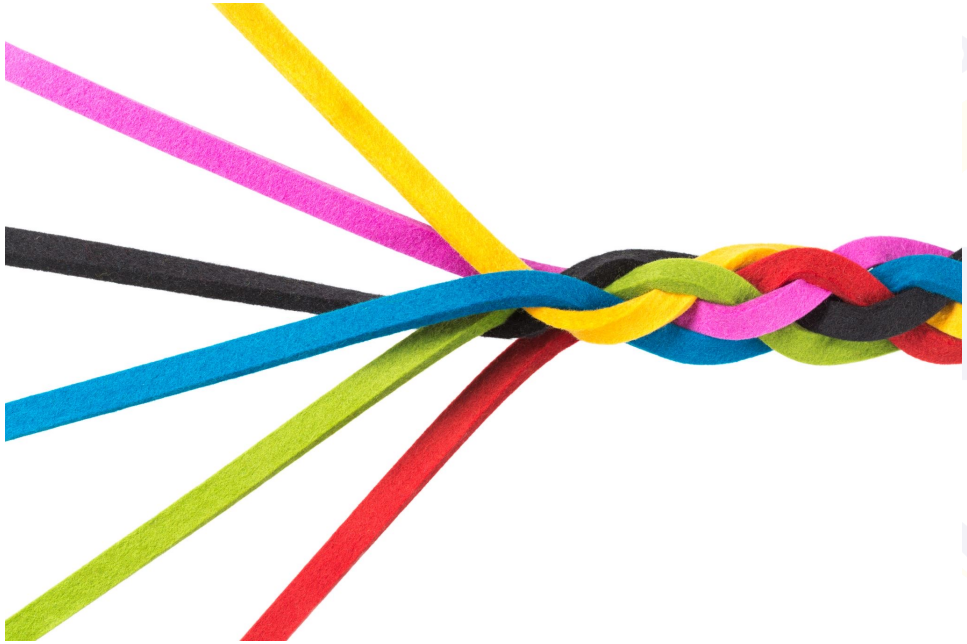
Objectives Of The Campaign

- To increase the awareness of the PLS and encourage registration of made-in-Ghana products
- To increase the number of locally made products in supermarkets and malls
- To encourage consumers to patronize locally made products to support our local industry

Specific Support to MSMEs

1. **Capacity Building:** As part of the PLS, the FDA provides technical support and training to help businesses understand and comply with regulatory requirements. This support includes guidance on GMP, quality control, packaging, labeling, and product testing.

Specific Support to MSMEs



2. Regulatory Harmonization:

Collaboration with the Ghana Standards Authority (GSA) to streamline certification processes, reducing costs and time for MSMEs.

Specific Support to MSMEs

3. Made-In-Ghana Sales: The FDA encourages supermarkets to organize month-long special Made-In-Ghana sales, for instance during festive occasions, intended to increase patronage and sales in made in Ghana products.

Specific Support to MSMEs

4. Promotional Efforts: Funding and airing of promotional videos to raise awareness of the BGLG campaign. As well as promotional activities at fairs and exhibitions across the country.

Impact

- **Enhanced Product Safety**: From 2019 till date, the FDA has licensed over 2,300 facilities and registered over 10,500 products under the PLS initiative. As these businesses have progressed through the stages of the PLS, the quality and safety of the products they produce have also greatly improved.

- **Facilitating Local and International Trade:** The PLS initiative has significantly improved market access for MSMEs, enabling them to not only thrive locally but also expand into international markets. Through capacity building and regulatory support, these businesses are now better equipped to meet international standards, enhancing their readiness to trade under the African Continental Free Trade Area (AfCFTA).

Impact

- **Promotional Activities**: The FDA has actively promoted the PLS initiative and made-in-Ghana products at key platforms, including manufacturers' associations, national fairs, and MSME-focused events such as the UNDP MSMEs Nimdee Series and the GIZ Annual Regional Network Conference for Enterprise Development and Employment Promotion. These efforts have increased visibility, stakeholder engagement, and support for local enterprise development.

Challenges Encountered

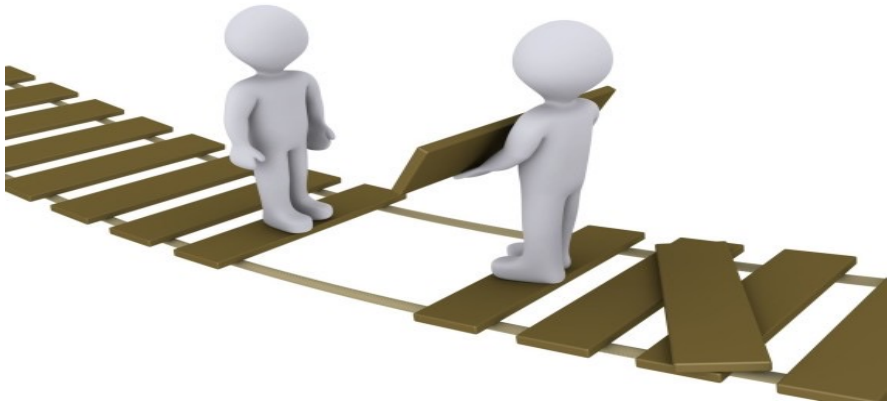
•**Supply Constraints:** Some local manufacturers are unable to meet the demand of supermarkets

•**Barcode Issues:** Many local products lack barcodes, hindering acceptance in retail outlets.

Challenges Encountered

- **Merchandising Conflicts:** Resistance of some supermarkets to provide dedicated stands for made-in-Ghana products

- **Data Gaps:** Insufficient data on the proportion of made-in-Ghana products versus imported brands
- **Funding:** Lack of funding in promoting the campaign



Conclusion

•The FDA is dedicated to supporting SMEs and promoting made-in-Ghana products.

•The FDA aims to contribute to the growth of the national economy through enhanced local and international trade.

•The FDA encourages stakeholders to collaborate to achieve the aim of 60% Made-in-Ghana products in all retail outlets.

CALL to ACTION

THANK YOU

ANY QUESTIONS PLEASE?

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