FOOD AND DRUGS AUTHORITY

2023 ANNUAL REPORT

JUNE 2024

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CEO'S END OF YEAR STATEMENT

By God's grace alone, we have come to the end of another milestone year. 2023 has been a year like no other, and we must thank God for the blessings and challenges we experienced. His providence has been our guiding light. It is with profound humility that we acknowledge the wisdom He bestowed upon us, enabling the Food and Drugs Authority (FDA) to weather the unique challenges of 2023.

On behalf of Management and staff, I extend my heartfelt gratitude to the Chairman of the Governing Board, the Members of the Governing Board and Board Committees, our Technical Advisory Committees, and our development partners for their unwavering support and guidance throughout this challenging yet remarkable year. Together, we have navigated uncharted waters, and I am profoundly thankful for the collaboration and leadership that have defined our journey.

In managing our human resource challenges, we have continued to utilize national service personnel, increasing our intake by about 50% for the 2022/23 period to 400 personnel. Their invaluable support in scouting, market surveillance, public education, and inspection of storage facilities has been instrumental in maintaining the integrity and efficiency of our operations. Despite the challenges affecting our targets, even at the end of the third quarter, I am proud to announce that as of the end of November 2023, the FDA had surpassed its targets for key performance indicators of product registration, facility licensing, market surveillance, quality control testing, and public education. This achievement is a testament to your commitment and sense of duty.

As we step into a new year, I urge staff to keep the organization's vision in mind in everything you do. Becoming a Centre of Excellence cannot happen if we don't share the vision and if everyone decides to go their own way. We will not get far if we do that. That's why I like Ubuntu, an ancient African word meaning 'humanity to others.' It reminds us that 'I am what I am because of who we all are.' Our very mandate revolves around humanity to others in our efforts to protect public health and safety.

Upholding our values of accountability, integrity, and teamwork has been the cornerstone of our success, and I urge each member of the FDA family to continuously embody these principles in all their dealings. We cannot allow self-seeking, self-absorption, or thoughtlessness to disorganize us or set us back. Disorganization leads to depletion—like trying to fit clothes in a bag without folding or ironing them.

As we conclude this chapter and embark on a new one, let us carry forward the lessons learned, the victories won, and the spirit of unity that defines us. In closing, let us look ahead with optimism and anticipation. Our journey is far from over, and I am confident that with God's wisdom, the challenges we face will only serve to strengthen our resolve. I expect all our employees to remain committed, focused, and continue striving towards our goals and many more successes!

Dr. Delese. A. A. Darko
CEO, Food and Drugs Authority

EXECUTIVE SUMMARY

The Food and Drugs Authority (FDA) is the national regulatory agency 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, vaccines, biological products, cosmetics, medical devices, household chemical substances and clinical trials oversight, and the control and use of tobacco and tobacco products, through the enforcement of relevant local and international standards to protect public health in Ghana. This report gives an account of the FDA's performance in the execution of its core mandate for the period January – December 2022.

Product Registration

In 2023, the FDA received a total of Twenty Thousand Six Hundred and Eighteen (20,618) product registration applications, a Seven percent (7%) decrease from the previous year performance. The authority however processed 22,181 product applications, comprising submissions made in 2023, as well as carryover of unprocessed applications from preceding years. Eighteen Thousand Two Hundred and Thirty (18,230) products were successfully registered, a seven percent (7%) increase compared to 2022. Four Thousand Eight Hundred (4,800) product applications were however deferred due to non-compliance with registration requirements, which includes but not limited to labelling, indication issues, and failure to meet quality control standards.

The FDA's Progressive Licensing Scheme (PLS) continues to play a vital role in assisting micro, small, and medium-scale enterprises (MSMEs) in achieving regulatory compliance for expedited market entry. Since its establishment, the program has facilitated the registration of Eight Thousand Seven Hundred and Twenty-Four (8,724) products, including food, cosmetics, and household chemical substances. This initiative underscores the FDA's dedication to creating a regulatory environment supportive of MSMEs, ensuring their products adhere to required standards while streamlining their access to the market. In 2023, One Hundred Forty-Five (145) food products and One Thousand Four Hundred Fifty-Four (1,454) cosmetic products were registered.

Facility Licensing

The number of licensing applications received increased from Six Thousand, Four-Hundred and Sixty-Eight (6,468) to Seven Thousand Nine Hundred and Seventy-Eight (7,978) during the reporting period. The FDA conducted Seven Thousand and Twelve (7,012) licensing inspections, marking a Twenty-two percent (22%) increase over the 2022 figures. In total Three Thousand, Nine Hundred and Sixty-Seven (3,967) facilities were licensed in 2023, an Eighteen percent (18%) increase compared to the previous year. Across the country, a total of Eleven Thousand and Thirty-Eight (11,038) inspections were conducted marking a 12% increase from the previous year's performance of Nine Thousand Eight Hundred and Twenty-Nine (9,829) inspections.

Market Surveillance

In 2023, the FDA conducted a total of Two Thousand Eight Hundred and Eighty-Nine (2,889) market surveillance outings were carried out nationwide, a significant increase of One Hundred and Seventeen percent (117%) compared to the previous year. Additionally, the number of outlets visited increased by Seventy-Three (73%), with Twenty-Six Thousand Three Hundred Thirteen (26,313) outlets visited. During these operations, Thirty-Eight Thousand One Hundred and Five (38,105) non-compliant products were identified, a 60% decrease from previous years.

Product Quality Testing

The Centre for Laboratory Services and Research (CLSR) received Five Thousand Five Hundred and Fifty-Five (5,555) samples for testing in 2023, representing a Forty-One percent (41%) increase over the previous year. Of these samples, ninety-three 93% were analysed, reflecting an increase of 0.76% from the previous year's performance.

Safety Monitoring of Medical Products

In 2023, the FDA received One Thousand Six Hundred and Forty-Two (1,642) Individual Case Study Reports (ICSRs), marking a Forty-Two percent (42%) decrease from 2022. However, Two Thousand Eight Hundred and Seven (2,807) ICSRs were entered into the safety watch system, encompassing reports received in 2023 and carryovers from the previous period.

Among these reports. One Thousand and Ninety-Eight (1,098) serious Adverse Events Following Immunization (AEFIs) were reviewed by the Technical Advisory Committee (TAC) on Safety Monitoring (SM), TAC on Vaccine Benefits and Policy (VBP), and the Joint Monitoring and Verification Committee (JMVC).

Five potential safety concerns were identified under the period under review: anaemia (5 reports), jaundice (4 reports), aggression (2 reports), difficulty breathing (2 reports), and thigh pain (1 report). Validation of these concerns is still underway.

Food Safety Coordination and Consumer Education

A total of Forty-Four (44) food safety alerts were received in 2023, indicating a 69.23% increase compared to 2022. The increased number of incidents and outbreaks recorded during the year highlights the effectiveness of alert monitoring strategies implemented by the department. There was a decrease in the number of local emergencies compared to 2022. During the period, suspected pathogens associated with the recorded foodborne outbreaks comprised Vibrio cholera, Staphylococcus aureus, Anthrax, and Salmonella sp.

Import and Export Control

Out of the Seventy-One Thousand Eight Hundred and Thirty-Six (71,836) permit applications received, Seventy-One Thousand and Forty (71,040) were processed in 2023, a Two percent (2%) increase from the previous year. Sixty-Six Thousand Eight Hundred and Ten (66,810) permits were approved, Two percent (2%) increase compared to the previous year. The number of import and export consignments inspected slightly increased by 1%, from Twenty-Three Thousand Nine Hundred and Fifty-Three (23,953) inspections in 2022 to Twenty-Four Thousand One Hundred and Fourteen (24,114) import and export inspections.

Clinical Trial Authorization

The number of fresh clinical trial applications received and reviewed increased from Fifteen (15) in 2022 to Twenty-Three (23) in 2023. There were fewer amendment applications received compared to 2022. The submission of additional clinical trial-related documents and interdepartmental documents decreased from 2022 to 2023, resulting in an overall reduction

in total submissions. This decline is attributed to the termination of some studies, particularly Covid-19 studies, due to a lack of study participants.

Technical Assistance to Industry

Significant milestones were achieved within Authority in the past year. Industrial Support Services Directorate successfully piloted the GMP Compliance Roadmap for Herbal Medicine Manufacturing Companies during a stakeholder meeting, aiming to ensure quality standards in the herbal medicine sector. Additionally, technical support was initiated for Bleach Manufacturers whose products did not meet the required standards, demonstrating FDA's commitment to regulatory compliance and product safety. A total of One Hundred and Two (102) requests for gap assessments were received, with Eighty-Six (86) comprehensive assessments conducted, spanning various sectors including food manufacturing, bleach manufacturing, and pharmaceuticals.

Capacity Strengthening

The FDA Ghana conducted extensive training sessions to enhance industry standards across various sectors. Three Hundred and Seventy-One (371) participants from One Hundred and Thirty (130) food manufacturing companies underwent training to ensure compliance with Good Manufacturing Practices (GMPs). Additionally, Six Hundred and Forty-One (641) participants from One Hundred and Thirty (130) food service establishments received training in food safety and hygiene practices. Training in good distribution practices was Twenty-Four (24) participants from Sixteen (16) pharmaceutical companies whiles One Hundred and Thirty-Five (135) participants from twenty-four (24) pharmaceutical companies were trained in good warehousing practices. Five Hundred and Thirty-Three (533) participants from eleven companies were trained in good cold storage practices. Sixteen (16) participants from Two (2) facilities were also trained in the introductory course of Hazard Analysis and Critical Control Points (HACCP). These efforts underscore the FDA's commitment to enhancing industry standards.

Tobacco and Controlled Substances Control

In 2023, Twenty-Two (22) applications were received, with Eighteen (18) were granted approval. Three (3) applications were deferred pending submission of additional documentation, while one (1) was carried over from the previous year. Import permit applications for controlled substances totalled Two Hundred and Sixteen (216) with One Hundred and Sixty-One (161) permits granted for importation. Notably, there was a 5%

increase in permits issued compared to the previous year, along with a significant rise in permits rejected due to incomplete information on the application form.

Public Awareness and Education

A total of Two Thousand and Seventy-Seven (2,077) educational campaigns were organized, reaching Three Million, Nine Hundred and Ten Thousand, Seven Hundred and Seventy- Six (3,910,776) individuals across various settings including schools, marketplaces, transport terminals, and media platforms. The focus of the educational efforts spanned critical areas including food and drug safety issues and tobacco awareness.

Business Development and International Partnerships

In 2023, the FDA onboarded thirty-six (36) partners and collaborators, securing commitments totalling One Million Eight Hundred Eighty-Eight Thousand One Hundred Seventy-Five US Dollars And Seventy-Seven Cents ($1,888,175.77) to bolster various regulatory systems strengthening initiatives. Noteworthy commitments were received from European Union - Deutsche Gesellschaft für Internationale Zusammenarbeit (EU-GIZ), United States Agency for International Development/United States Pharmacopeia (USAID/USP), Paul-Ehrlich-Institut (PEI), Physikalisch-Technische Bundesanstalt (PTB), World Health Organization (WHO), African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD), Coalition for Epidemic Preparedness Innovations (CEPI), and Centers for Disease Control and Prevention/Centers for Disease Detection (CDC/CDD) and the Bill and Melinda Gates Foundation. These partnerships have facilitated numerous projects, including the construction of an ISO Class 7 cleanroom with an ISO Class 8 background, procurement of laboratory equipment, the upgrade of the Laboratory Information Management System (LIMS) from 2.0 to 4.5, the implementation of the Integrated Regulatory Information Management System (IRIMS), designed to streamline regulatory processes and improve operational efficiency across the organization, and the upgrade of the existing FDA website.

Notable training sessions sponsored by partners include hands-on training in Quality, Non-Clinical, and Clinical Assessment of Vaccine Dossiers for forty (40) FDA staff and a hands-on training program on Good Manufacturing Practices in Vaccine Manufacturing at the Biotech Training Facility in Leiden, Netherlands for eight (8) FDA staff. The FDA also facilitated study tours for about thirty-five (35) regulators from Rwanda, Guinea, Mozambique, Senegal, South

Africa, and Botswana, emphasizing our commitment to knowledge exchange and regulatory advancement on the continent.

With support from its partners, the FDA organized its maiden FDA Scientific Forum under the theme "Protecting Public Health and Safety through Partnerships," fostering critical dialogue and strategic partnerships among regulatory authorities, industry stakeholders, and academia.

Additionally, the FDA participated in COP28 with support from GIZ for the first tproime. Following this meeting, in collaboration with Zoomlion Ghana Limited, the Authority is working on a staff waste recycling programme and the exploration of improved environmentally friendly solutions for safe disposal of FDA-regulated products.

Certification and Accreditations

The Authority maintained its ISO 9001:2015 certification for both technical and administrative functions.

The Centre for Laboratory Services and Research also maintained its ISO 17025:2017 accreditation for 58 tests during the year under review.

Finance

Total revenue of One Hundred and Eighty-Four Million, Two Hundred and Twenty-Four Thousand, Eight Hundred and Forty-Five Ghana Cedis, Fifty-Two Pesewas (GHS 184,224,845.52) was collected in 2023, representing a 31% increase compared to the previous year. Out of this amount, Forty-Seven Million, Two Hundred and Thirty-Five Thousand, Six Hundred and Eighty Ghana Cedis, Forty-Four Pesewas (GHS47,235,680.44) was transferred to the consolidated fund.

Internal Audit

All payroll reviews were completed, along with requests for the review of goods supplied to FDA stores. In the financial year 2023, One Thousand Eight Hundred and Thirty-One (1,831) payment vouchers (PVs) were reviewed and One Thousand Eight Hundred and Nine (1,809) were recorded in the PV register, with Twenty-two (22) PVs returned due to non-compliance issues, ensuring adherence to financial regulations and accountability. The non-compliant issues identified included Non-Withholding of Tax on Payment, Discrepancies Between Budget Amounts and PV Amounts, Difficulties in Accessing Supporting Documents, Non-Attachment of Essential Supporting Documents, Errors in Computation, Duplication of PVs,

Unauthorized Rates for Allowance Claims, Inaccurate Tax Calculations, Mislabelling of Supporting Documents, Submission of Invoices Exceeding Approved Budgets, Inaccuracies in Overtime Calculations, Wrong Payee Names or Currency Accounts, .These findings highlight the necessity for meticulous attention to detail and strict adherence to established procedures in the payment process.

Conclusion

The year 2023 witnessed enhancements in performance across various sectors, resulting in operational and financial achievements. The FDA remains committed to bolstering its endeavors to safeguard public health and safety through rigorous regulatory measures and capacity-building initiatives.

1.0 INTRODUCTION

The Food and Drugs Authority (FDA) is mandated by Parts 6, 7 & 8 of the Public Health Act 2012, Act 851 to safeguard public health and safety by implementing regulations that ensure the quality, safety, and efficacy of various products including food, allopathic medicines, herbal medicines, veterinary medicines, vaccines, biological products, medical devices, cosmetics, household chemical substances, tobacco and tobacco products, as well as substances of abuse. Additionally, the FDA is responsible for authorizing and overseeing the conduct of clinical trials. Over the years, the FDA has adapted to evolving threats to public health and safety, as well as advancements in product development and manufacturing technologies.

Continuing its commitment to ensure public health and safety, the FDA strives to improve its internal processes to establish itself as a global leader in food and medical product regulation. The results of the 2022 client satisfaction and public confidence survey, conducted in the first quarter of 2023, demonstrated a customer satisfaction index of 82% and a Public Confidence Index of 83.6%. As an organization, we remain dedicated to fostering a culture of accountability, teamwork, and integrity, aiming to elevate the level of confidence our clients and the public have in the FDA.

The ongoing development of the web-based product registration system, Integrated Regulatory Information Management System (IRIMS) solution which encompasses a comprehensive set of functionalities to efficiently manage all regulatory processes of the Food and Drugs Authority is poised to revolutionize our operations. This system will streamline the product registration process, decentralize evaluation procedures, and ultimately enhance operational efficiency at the FDA.

1.1 Vision

To protect the health and safety of people in Ghana and to be a global Centre of excellence for food and medical product regulation

1.2 Mission Statement

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.

1.3 Critical Success Factors

The 2020-25 Strategy Compass of the FDA espouses the following critical success factors:

i. Financial Performance - Attain financial sustainability driven by prudent and innovative resource management.
ii. Clients - Achieve the highest quality of service delivery that aligns with our purpose.
iii. Processes - Achieve system-wide effectiveness and efficiency using cutting edge technology as an enabler. iv. People - Build motivated and highly skilled teams, delivering performance in a model Public Sector institution.
v. Partnerships - Nurture relationships that support our ambition of excellence.

1.4 Core Values

The core values which define the work culture within the organization are as follows:

i. Accountability
ii. Teamwork
iii. Integrity

1.5 Functions of the Food and Drugs Authority

The functions of the FDA as spelt out in parts six (6), seven (7) and eight (8) of the Public Health Act, 2012 (ACT 851) Act 851; these are reflected by the respective Technical Divisions and Departments as well as Regional Offices within the organization. The daily activities of all operational units of the FDA find their place within the following:

1. 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.

2. Register food, human (allopathic and herbal) and veterinary drugs, biological products, cosmetics, household chemical substances, medical devices and tobacco products.

3. License facilities for manufacture and storage, and vehicles for the transportation of FDA regulated products.
4. Issue food hygiene permit for food service establishments, meat shops, abattoirs and slaughter slabs.
5. Issue import and export permits for FDA regulated products.
6. Free-sale certificate for export of FDA regulated products.
7. Carry out market surveillance of FDA registered products.
8. Monitor adverse effects in the use of FDA regulated products.
9. Approve and monitor advertisement of FDA regulated products.
10. Investigate consumer complaints for FDA regulated products.
11. Provide industrial support services to manufacturers of FDA regulated products.
12. Provide clients services to companies and individuals.
13. Monitor FDA regulated products at all ports of entry.
14. Approve the initiation and conduct of clinical trials.
15. Test all FDA regulated products to ensure conformance to all relevant standards.
16. Educate the public on safe handling and use of FDA regulated products.
17. Monitor through the District Assemblies and any other agency of State, compliance with the provisions of Parts 6, 7 and 8 of Act 851.
18. Develop effective Regulations for the implementation of Parts 6, 7 and 8 of Act 851.
19. Advise the Minister on measures to protect public health.

This report gives an account of the FDA's performance in the execution of its core mandate for the period January – December 2023.

2.0 MANAGEMENT AND STRUCTURE OF FDA

FDA Governing Board

The 6th FDA Governing Board is made up of eleven (11) members. See appendix 1 for updated membership list of the Governing Board.

Management Team

Executive Committee

Mr. Joseph Bernie Bennie, Head, Legal and Corporate Affairs Directorate, who served the Authority for Twenty-One (21) years retired from active service at the Food and Drugs Authority (FDA) on the 3rd of October, 2023 after reaching the statutory retirement age of sixty (60).

See appendix II for the updated list of members of the FDA Executive Committee

Middle Level Management

In the year under review, the team welcomed two new members: Mr. Jacob Amoako-Mensah, who assumed the role of Regional Head for the newly established Northeast Region, and Mrs. Gloria Asum Kwarteng, representing the Centre for Import and Export Control.

See appendix III for the updated list of members of FDA Middle Level Management.

Department Heads

During the reviewed year, a new department, the Satellite Laboratory Department, was established to oversee the operations of the minilabs within the regions and ports. This addition brings the total number of departments to forty-two (42).

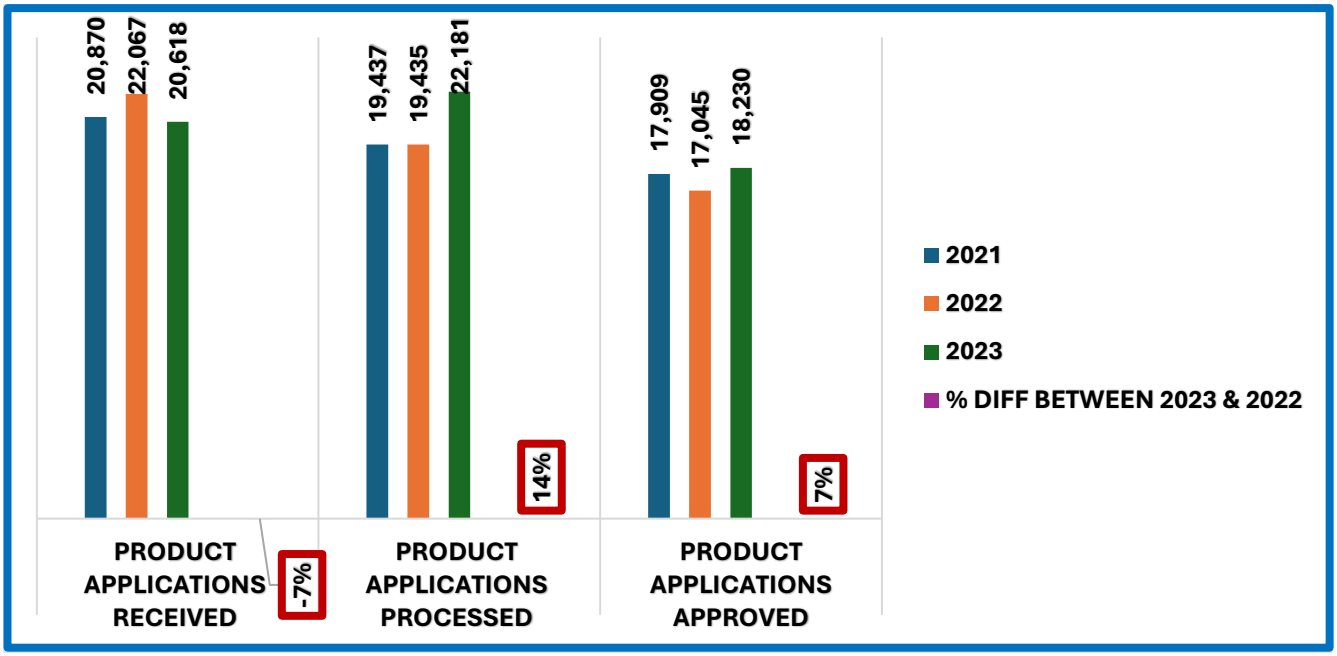
See appendix IV for the updated list of Department Heads.

3.0 2023 OPERATIONAL PERFORMANCE

3.1 Registration of FDA regulated products.

The FDA oversees product registration through seven specialized departments: Food Evaluation and Registration, Drug and Nutraceutical, Vaccines and Biological Products, Herbal and Homeopathic Medicines, Medical Devices, Tobacco and Tobacco Products, and Cosmetics and Household Chemical Substances Departments. The following graph depicts the performance trend in product registration for all FDA-regulated items spanning the years 2021 to 2023.

Figure 3.1-1: Performance trend for registration of FDA regulated products.



Source: FDA Planning, Monitoring and Evaluation Department (2023)

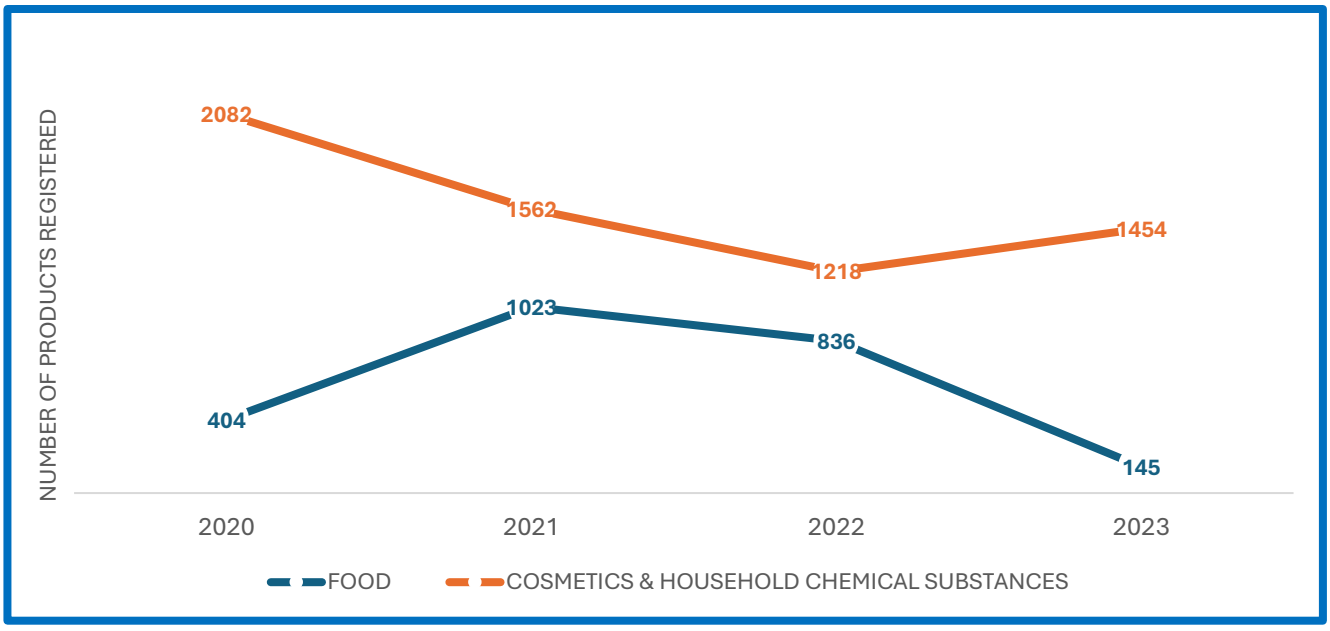
In 2023, the annual targets for product applications received and processed for all FDA-regulated products were set at Nineteen Thousand Seven Hundred and Sixty-Six (19,766) and Seventeen Thousand Two Hundred and Seventy (17,270) respectively. By the year's end, there were Twenty Thousand Six Hundred and Eighteen (20,618) product applications received, surpassing the annual target by achieving 104%. Out of these applications, Twenty-Two Thousand One Hundred and Eighty-One (22,181) were processed, exceeding the target by achieving 128%. Despite a 7% decrease in the number of products received compared to the previous year, there was a notable increase in registered products. In 2023, Eighteen Thousand Two Hundred and

Thirty (18,230) products were registered, marking a 7% increase over the previous year's performance of Seventeen Thousand and Forty-Five (17,045).

The FDA-regulated products register encompasses a diverse array of products essential for public health and safety. In total, the register has Fifty-Three Thousand Five Hundred and Ninety-Seven (53,597) products under FDA regulation. Food products lead the count at Twenty-Four Thousand Two Hundred Forty-Two (24,242) products, followed by Cosmetics & Household Chemical Substances with Seventeen Thousand Sixty-Three (17,063) entries. The Drugs & Nutraceuticals category comprises Seven Thousand Four Hundred Sixty-One (7,461) products, while Medical Devices total Three Thousand One Hundred Thirty-Five (3,135). Herbal & Homeopathic Medicines contribute One Thousand Five Hundred Fifty-Two (1,552) items, and Vaccines & Biological Products are represented by One Hundred Twenty-Six (126) entries. Tobacco & Tobacco Products conclude the list with Eighteen (18).

3.1.1 Progressive Licensing Scheme (products)

The FDA's Progressive Licensing Scheme (PLS) continues to play a vital role in assisting micro, small, and medium-scale enterprises (MSMEs) in achieving regulatory compliance for expedited market entry.



Source: FDA Planning, Monitoring and Evaluation Department (2023)

A total of Eight Thousand Seven Hundred and Twenty-Four (8,724) products, spanning food, cosmetics, and household chemical substances were registered under the Progressive Licensing Scheme (PLS) since inception. Notably, in 2020, Four Hundred Four (404) food

products and Two Thousand Eighty-Two (2,082) cosmetic products were successfully registered. However, by 2023, a shift occurred, with only One Hundred Forty-Five (145) food products and One Thousand Four Hundred Fifty-Four (1,454) cosmetic products being registered. This transition can be attributed to a decrease in applications from the Ghana Enterprise Agency (GEA) for cosmetic products.

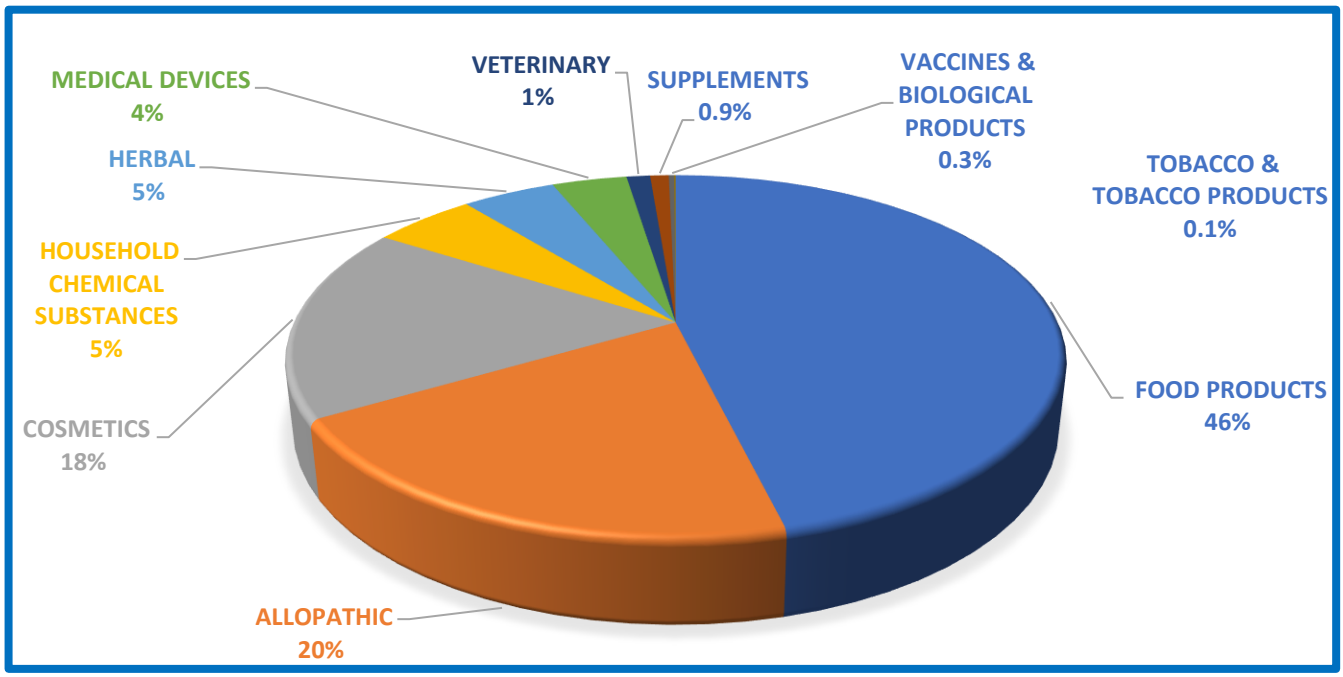
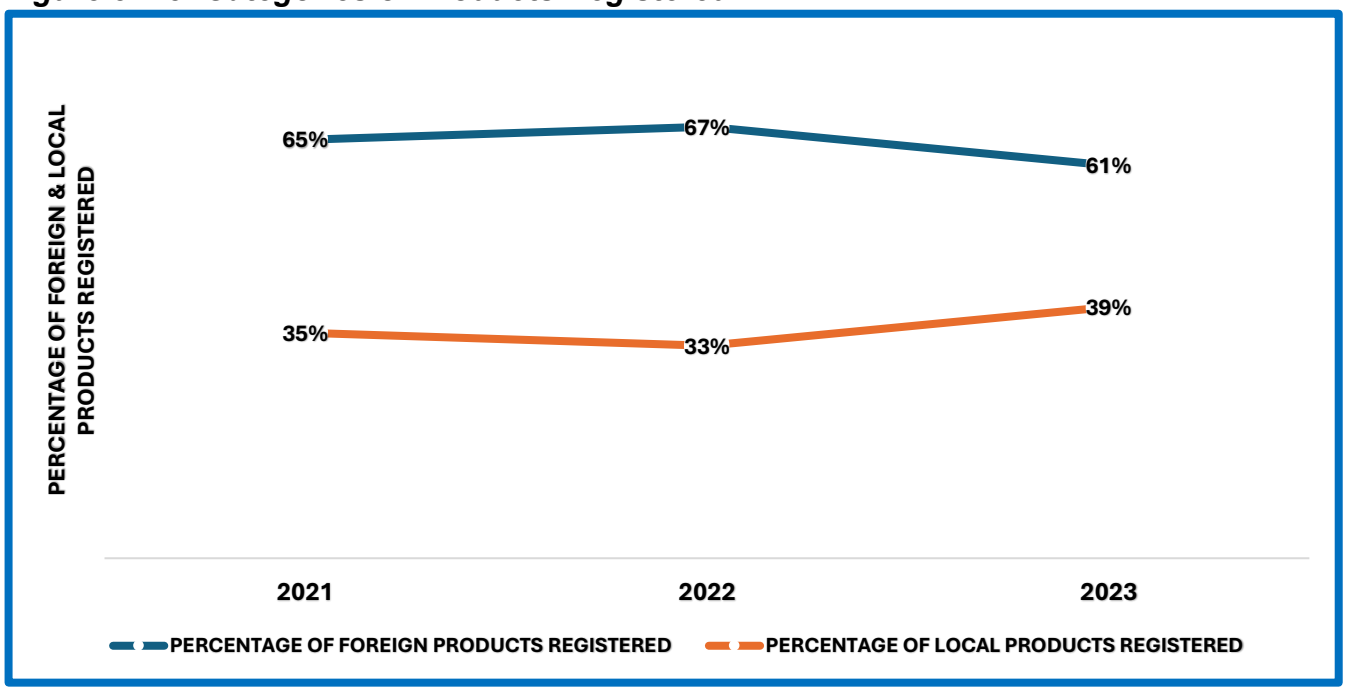


Figure 3.1-2: Categories of Products Registered
Source: FDA Planning, Monitoring and Evaluation Department (2023)

For the categories of products registered during the period under review, food was 46%, allopathic medicines, 20%, cosmetics, 18% with tobacco and tobacco products being the least with 0.1%.

Figure 3.1-3: Categories of Products Registered



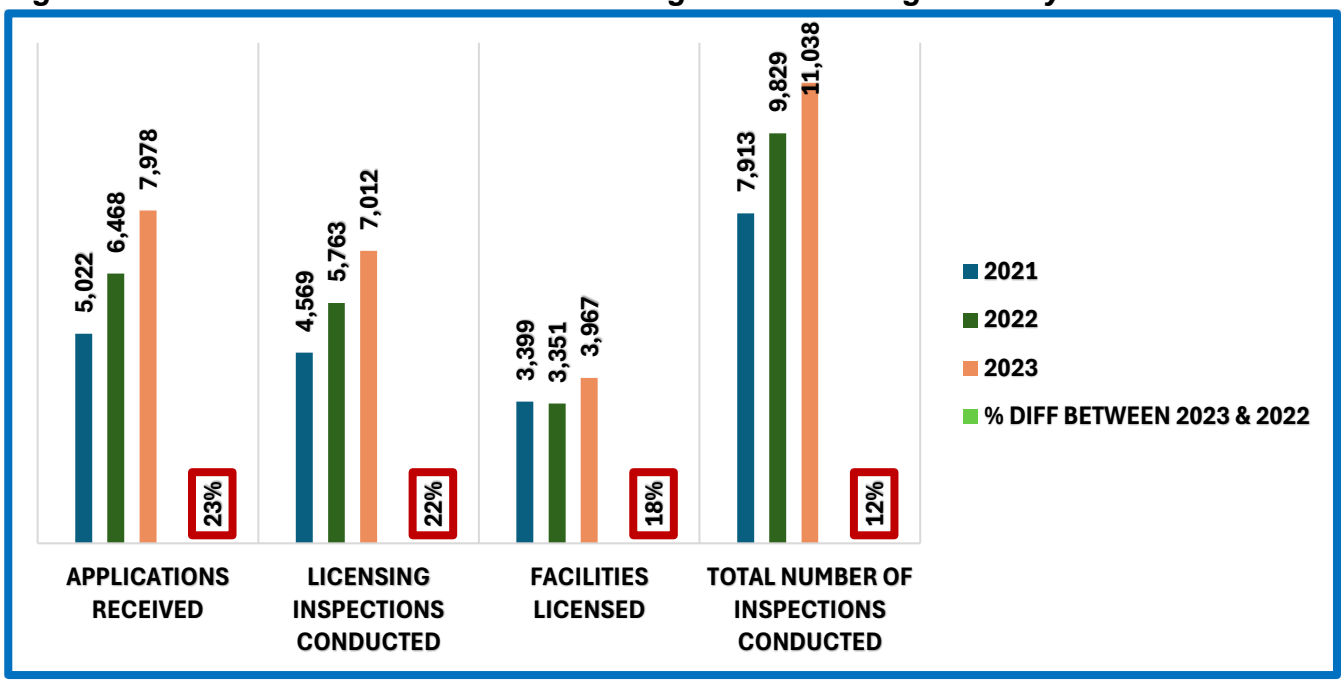
Source: FDA Planning, Monitoring and Evaluation Department (2023)

Over the years, the percentage of FDA-regulated products that are foreign and local were local. In 2022, the percentage of foreign products increased slightly to 67% (sixty-seven percent), with local products at 33%. In 2023, the trend shifted, with foreign products making up 61% (sixty-one percent) and local products rising to 39.

3.2 Licensing of facilities regulated by the FDA.

Licensing of facilities at the FDA is conducted by the Manufacturing Facilities, Storage Facilities, Food Services Establishments Departments, and regional offices. The FDA operates a centralized licensure system for facilities nationwide, managed from the Head Office in Accra.

Figure 3.2-1: Performance trend for licensing of facilities regulated by the FDA.

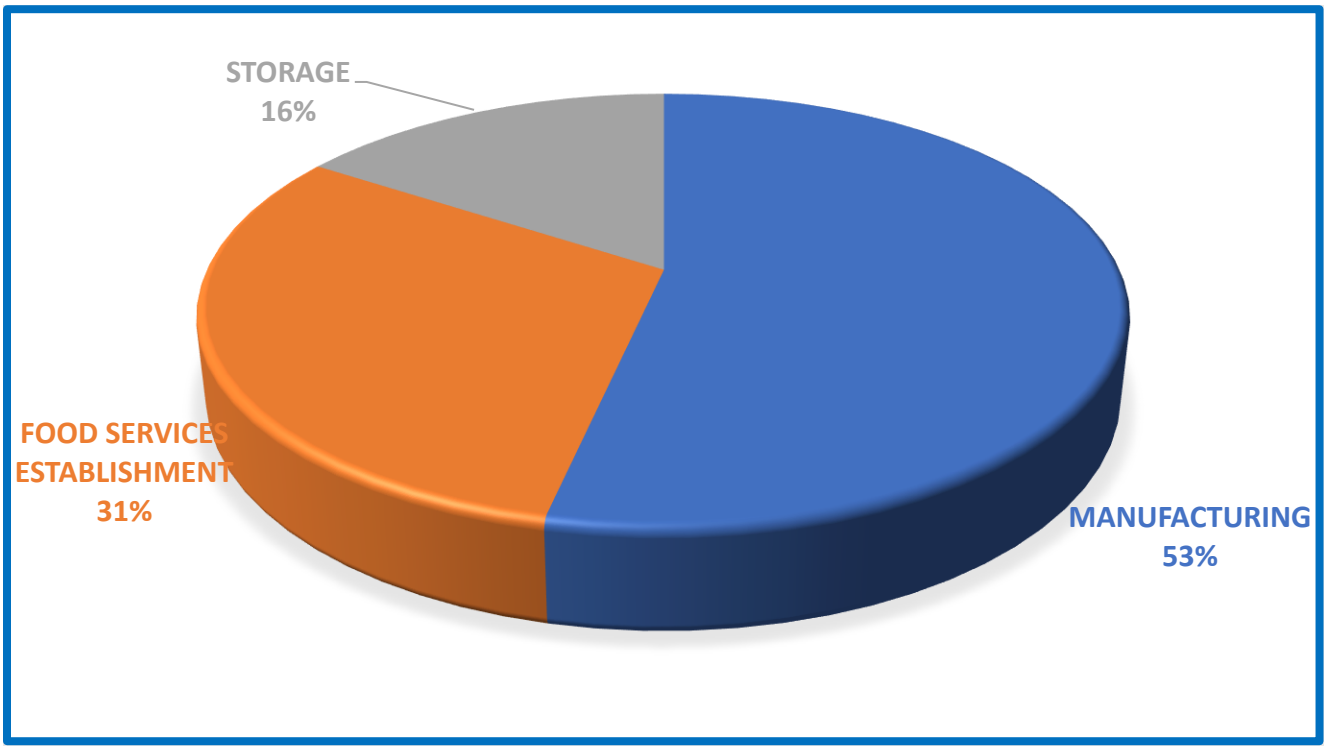


Source: FDA Planning, Monitoring and Evaluation Department (2023)

The 2023 target for facility applications received and licensing inspections conducted were set at Seven Thousand One Hundred and Fifteen (7,115) and Six Thousand Three Hundred and Thirty-Nine (6,339) respectively. By the close of 2023, a total of Seven Thousand Nine Hundred and Seventy-Eight (7,978) facility license applications were received, surpassing the annual target by 12%. Seven Thousand and Twelve (7,012) licensing inspections were carried out, resulting in the licensing of Three Thousand Nine Hundred and Sixty-Seven (3,967) facilities. This signifies a 22% increase in the number of inspections conducted and an 18% increase in the facilities licensed compared to the previous year's performance. The FDA remains committed to assisting industries in achieving regulatory compliance for their facilities. Overall, a total of Eleven Thousand and Thirty-Eight (11,038) inspections were conducted in 2023, a 12% increase compared to the previous year’s performance.

The figure below shows the categories of facilities licensed:

Figure 3.2-2: *Categories of Facilities Licensed*

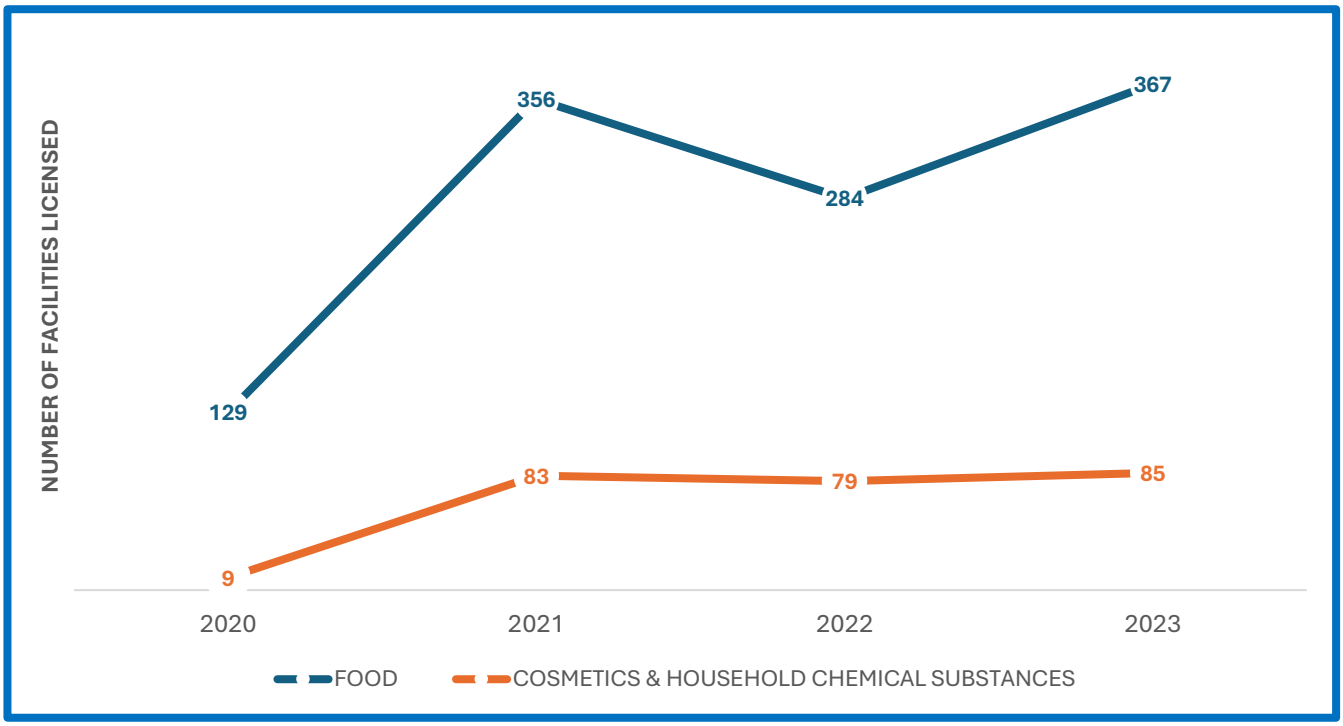


Source: FDA Planning, Monitoring and Evaluation Department (2023)

For the categories of facilities licensed, manufacturing facilities represented the highest proportion of (53%), with Food Services Establishments having the second highest of (31%), Storage facilities the third highest (16%). The FDA continues to work assiduously in bringing facilities across all categories into compliance.

Progressive Licensing Scheme (facilities)

Between 2020 and 2023, the FDA licensed a total of One Thousand Three Hundred and Ninety-Two (1,392) food and cosmetics and household facilities under the programme.

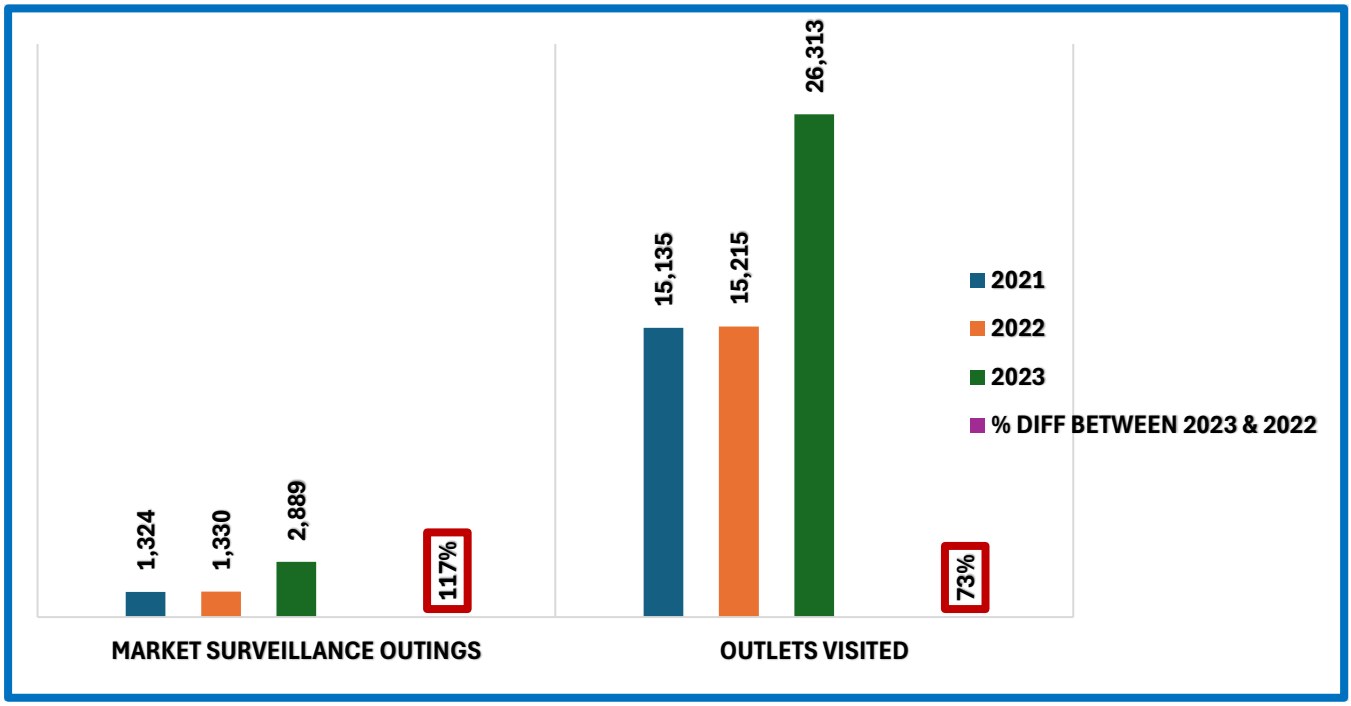


Source: *FDA Monitoring and Evaluation Department (2023)*

The number of licensed food facilities rose from One Hundred Twenty-Nine (129) in 2020 to Three Hundred Fifty-Six (356) in 2021, slightly decreased to Two Hundred Eighty-Four (284) in 2022, and then increased again to Three Hundred Sixty-Seven (367) in 2023. Similarly, the number of licensed cosmetics facilities surged from Nine (9) in 2020 to Eighty-Three (83) in 2021, slightly dropped to Seventy-Nine (79) in 2022, and rose again to Eighty-Five (85) in 2023.

3.3 Market surveillance operations

Figure 3.3-1: *Performance for market surveillance operations*

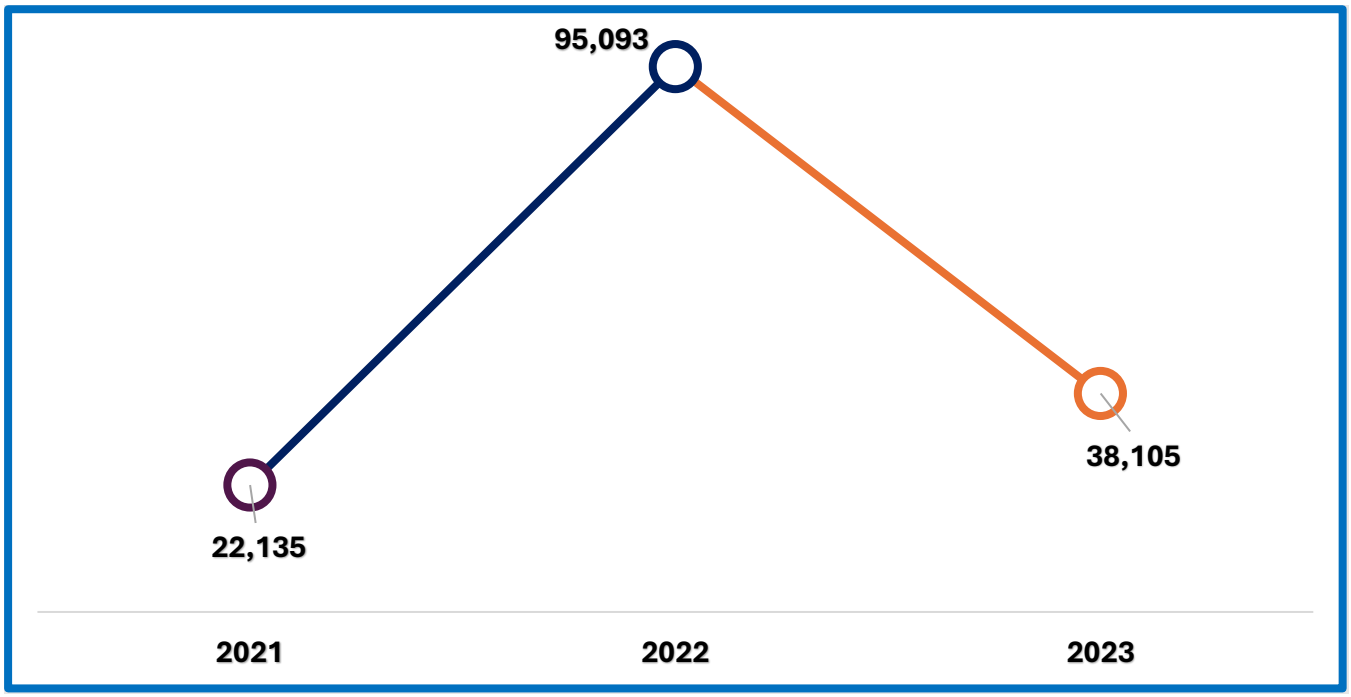


Source*: FDA Monitoring and Evaluation Department (2023)*

The 2023 annual target for the number of market surveillance outings and outlets visited were set at were One Thousand Four Hundred and Fifty-Six (1,456) and Sixteen Thousand Seven Hundred and Thirty-Seven (16,737) respectively. By the end of the year, the FDA had conducted Two Thousand Eight Hundred and Eighty-Nine (2,889) market surveillance outings across the country, exceeding its target by 197%, marking a 117% increase over the previous year's performance. Additionally, a total of Twenty- Six Thousand Three Hundred and Thirteen (26,313) outlets were visited in 2023, surpassing its annual target by 157%.

As part of the FDA's market surveillance operations, the Take Back Unwanted Medicines (TBUM) project retrieved Two Thousand Six Hundred and Twenty-One (2,621) unwanted medicines from pharmaceutical shops. Specifically, thirty-two (32) shops in Greater Accra, forty-one (41) in Ashanti, and thirty-six (36) in the Western Region participated in the initiative. Of the medicines collected, 61% were over the counter (OTC) medications, while 39% were prescription-only medications (POM)

***Figure 3.3-2**: Non-Compliant Products Identified in Trade*

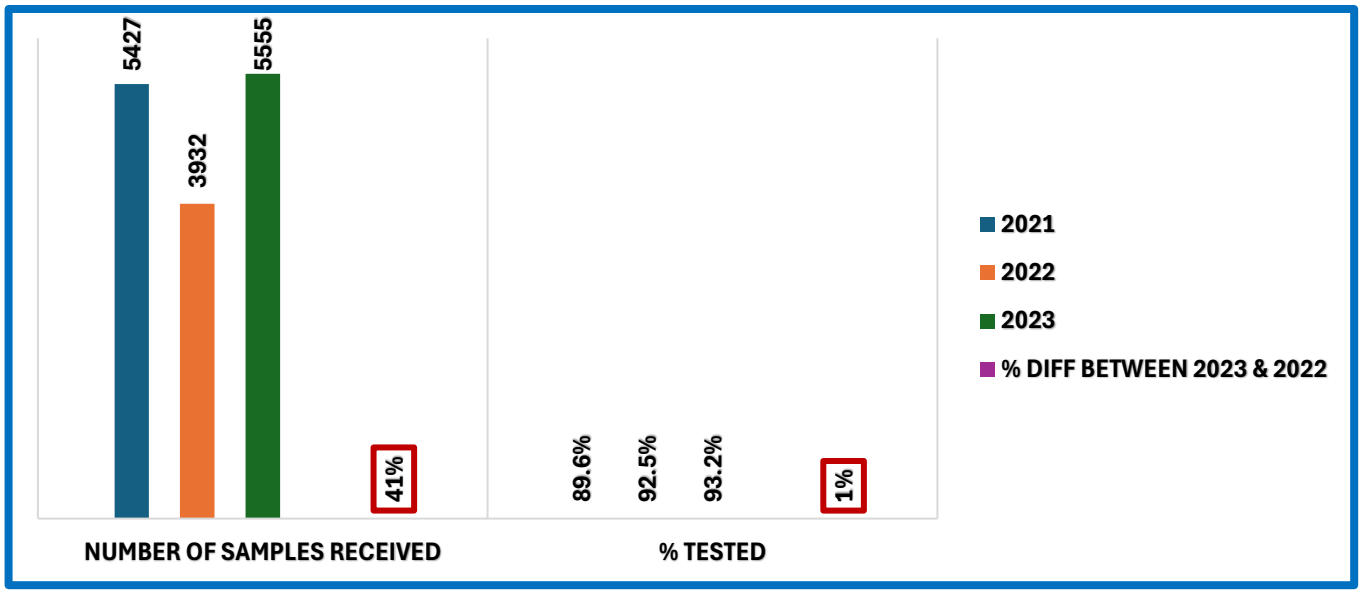


***Source**: FDA Planning, Monitoring and Evaluation Department (2023)*

In 2023, a total of Thirty-Eight Thousand One Hundred and Five (38,105) non-compliant products were identified in trade, marking a notable decrease of 60% compared to the previous year's performance. The significant spike observed in the 2022 figure can be attributed to various raids and swoops organized to confiscate certain pharmaceutical products based on intelligence gathered by the enforcement teams.

3.4 Product Quality Testing

Figure 3.4-1: Product Quality Testing Performance



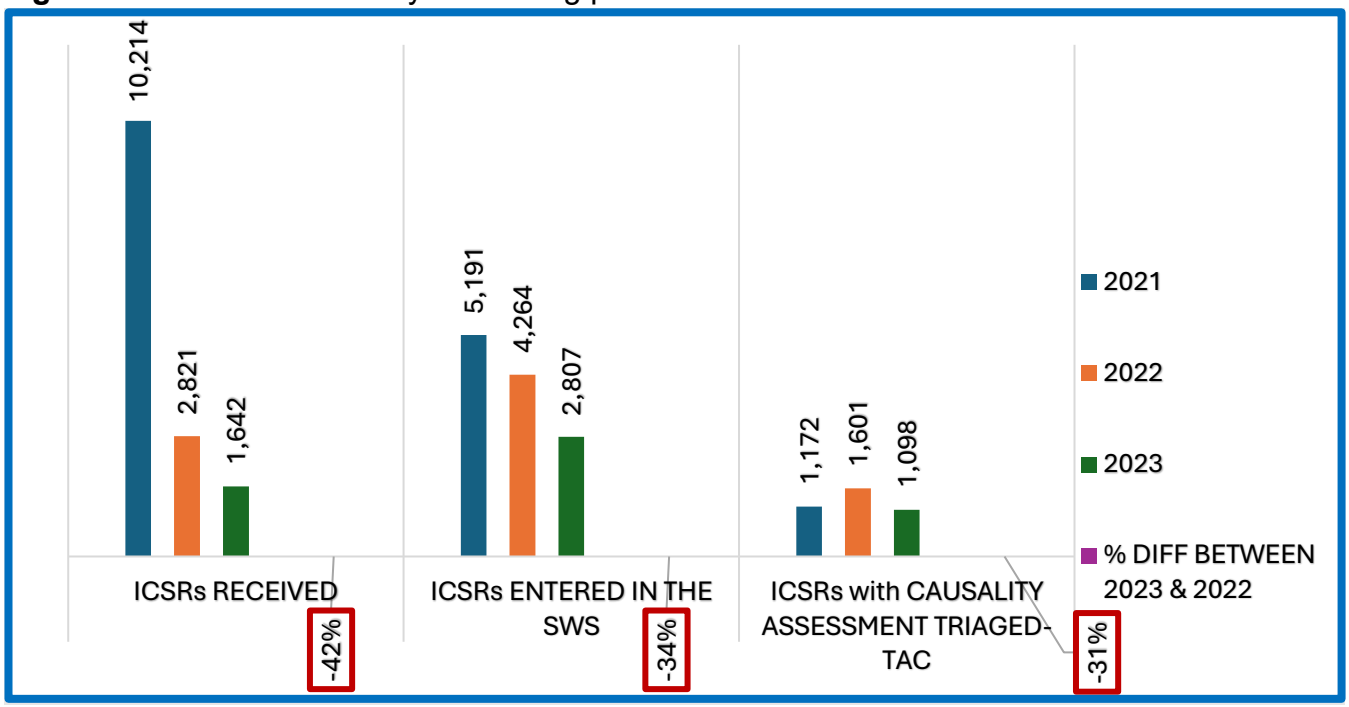
Source: FDA Planning, Monitoring and Evaluation Department (202*3)*

The Centre for Laboratory Services and Research (CLSR) of the FDA targeted to analyze 85% of all samples submitted to the Centre. In total, Five Thousand Five Hundred and Fifty-Five (5,555) samples were received by the CLSR for testing, reflecting a significant increase of 41.3% compared to the previous year. Out of these samples, 93.2% were tested, marking a slight increase of 0.8% over the previous year's performance. The ability to exceed the set target was attributed to the commitment of the centre's staff, who worked overtime to meet the set targets.

For ***product quality monitoring*** exercise in 2023, the FDA tested various products, resulting in a 53% pass rate for bleach products in Q1; a 63% pass rate for anti-diabetics, anti-hypertensive drugs, chlorpromazine 50mg injection, lithium carbonate 300mg, clozapine 100mg, benztropine 2mg from Rock Chemist, haloperidol injection from Max Health Pharmaceuticals Limited, amodiaquine 150mg + sulphadoxine/pyrimethamine 500/25mg tablets (batch 23001) supplied by Kina Pharma, and some anti-malarials in Q2; a 33% pass rate for bleach, paracetamol/vitamin C fixed dose combinations, haloperidol, and fluphenazine injection in Q3; and a 69% pass rate for vaccines, psychotropics, antihypertensives, antidiabetics, and antimalarials in Q4.

3.5 Safety Monitoring of Medical Products

Figure 3.5-1: Trend of safety monitoring performance



***Source**: FDA Planning, Monitoring and Evaluation Department (2023)*

The 2023 annual target for entering Individual Case Study Reports (ICSRs) into the safety watch system was set at 100%. By the year's end, a total of One Thousand Six Hundred and Sixty-Four (1,642) ICSRs were received, and Two Thousand Eight Hundred and Seven (2,807), including carryovers from the previous period, were entered into the system, surpassing the target by achieving 171%

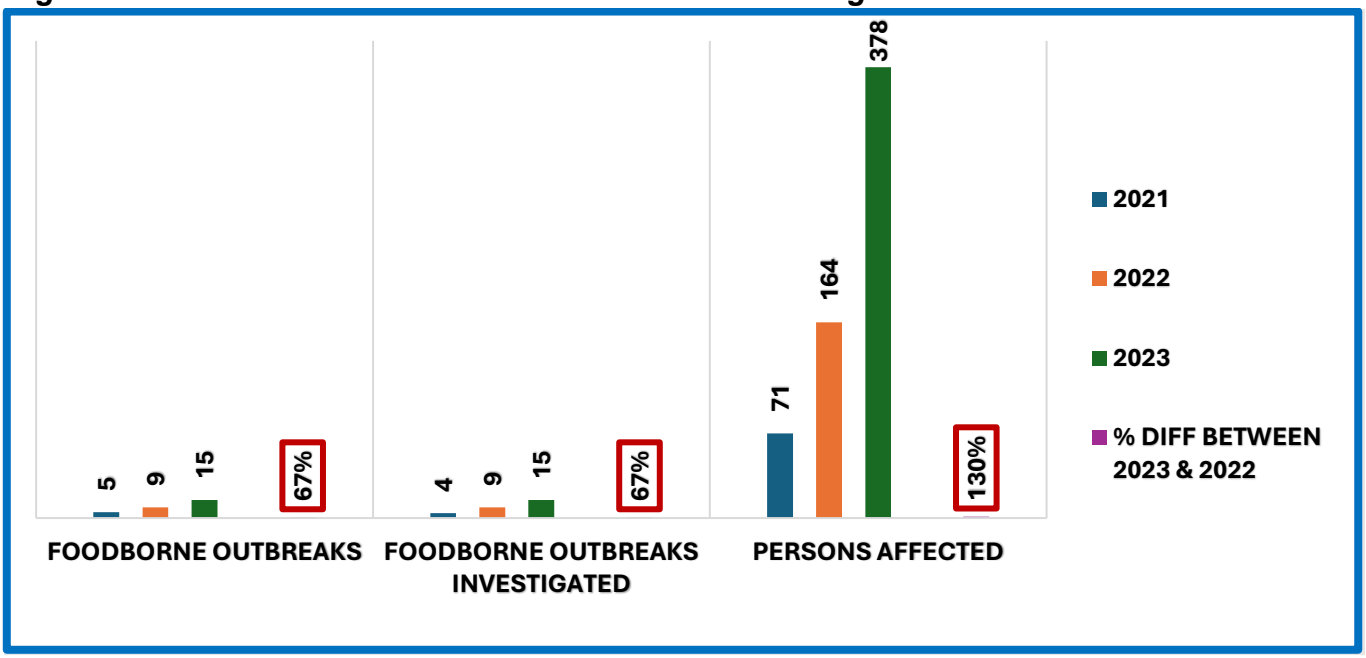
Furthermore, a total of Seventeen (17) Technical Advisory Committee (TAC) meetings were convened in 2023. The number of ICSRs presented to Advisory Committees decreased by 31% from One Thousand Six Hundred and One (1,601) to One Thousand and Ninety-Eight (1,098). During the new oral polio vaccination campaign (nOPV2), five potential safety concerns were identified, including cases of anaemia (5 reports), jaundice (4 reports), aggression (2 reports), difficulty breathing (2 reports), and thigh pain (1 report). Validation of these concerns is currently underway.

Healthcare professionals were informed about various issues, including the risk of anesthesia in individuals exposed to Pholcodine within 12 months before using neuromuscular blocking agents, the recall of Lupin's Quinapril Hydrochloride Tablets, enhanced risk management for Sodium valproate requiring changes to product information, and the detection of falsified Meronem IV in the Ghanaian market.

3.6 Foodborne disease outbreaks and investigations indicators for 2021-2023

Throughout the fiscal year, a total of fifteen (15) outbreaks were recorded nationwide, indicating a 67% increase compared to those documented in 2022. Consequently, the number of affected individuals surged by 130%, resulting in four (4) fatalities. This rise in both outbreak occurrences and affected individuals can be attributed to the specific nature of the outbreaks and the demographics of the affected populations, particularly concentrated in closed environments such as schools, prisons, and hotels.

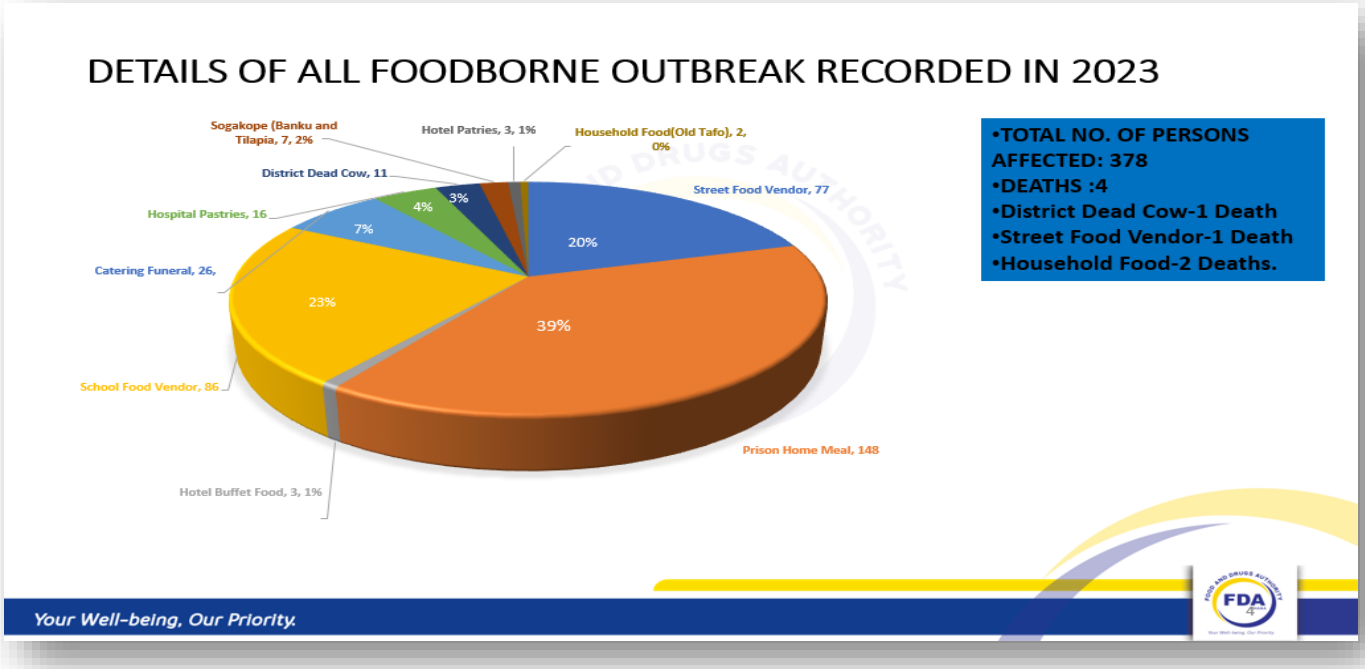
Figure 3.6-1: Food borne disease outbreaks and investigations for 2021-23.



Source: *FDA Planning, Monitoring and Evaluation Department (2023)*

Thorough investigations were launched for all recorded outbreaks, and by the close of 2023, 95% of these inquiries had been finalized, as detailed below:

Figure 3.6-2: Details of all foodborne outbreak recorded in 2023.

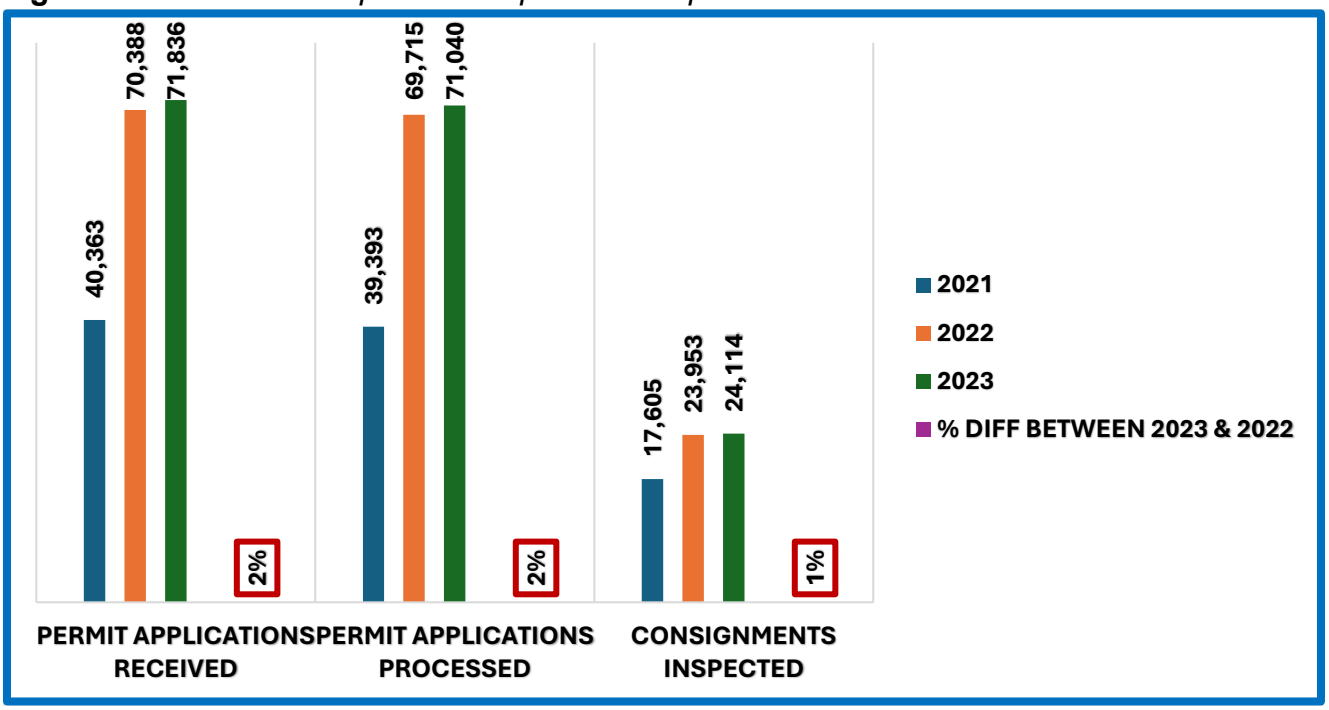


***Source**: FDA, Foodborne Disease Surveillance (2023)*

3.7 Import and Export Control

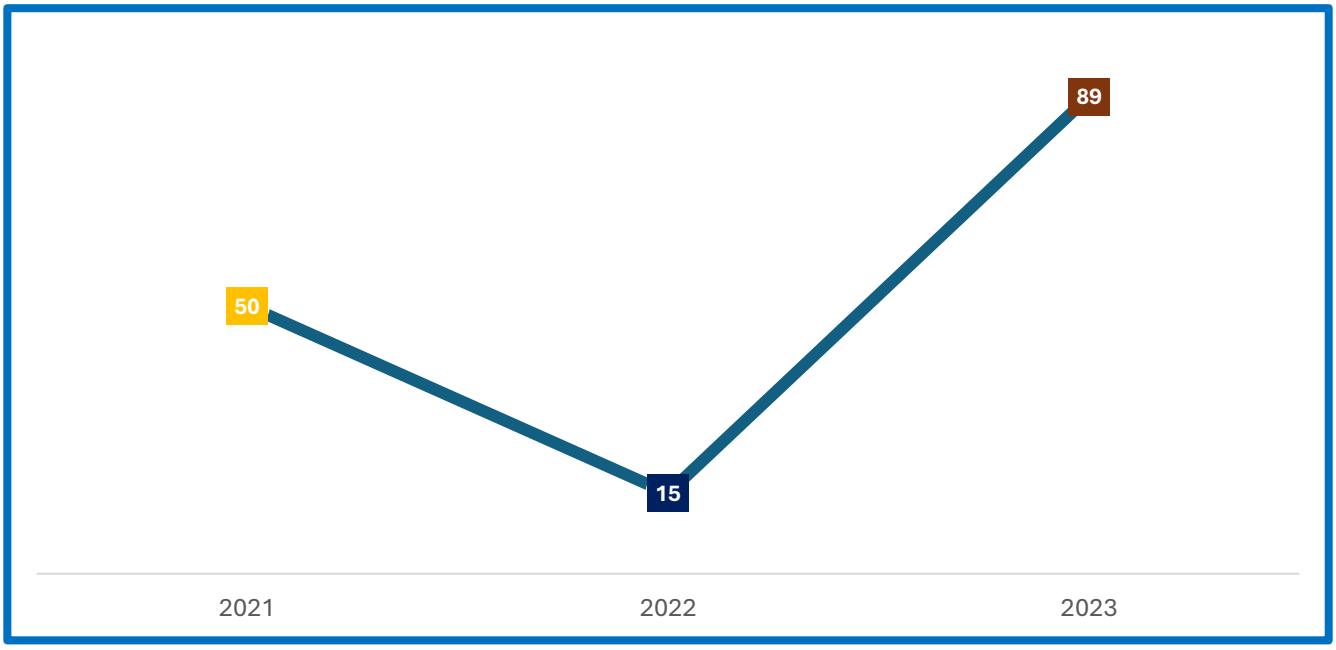
The target set for the number of permit applications to be received in 2023 was Seventy-Seven Thousand Four Hundred and Twenty-Seven (77,427), with the expectation of processing all received applications. By the year's end, a total of Seventy-One Thousand Eight Hundred and Thirty-Six (71,836) permit applications were received, achieving 93% of the annual target. Among these, Seventy-One Thousand and Forty (71,040) permits were successfully processed, representing 99% of the received applications, falling just 1% short of the annual target. The variance between applications received and processed primarily comprised those undergoing vetting procedures during the period. Additionally, the year saw the receipt of two (2) bonded warehouse applications, with one (1) being licensed.

Figure 3.7-1: *Trend of import and export control performance*



Source: FDA Planning, Monitoring and Evaluation Department (2023)

Figure 3.7-2*:* Trend of the Monthly Average Detentions for the No Registration No Clearance Programme



Source: FDA Planning, Monitoring and Evaluation Department (2023)

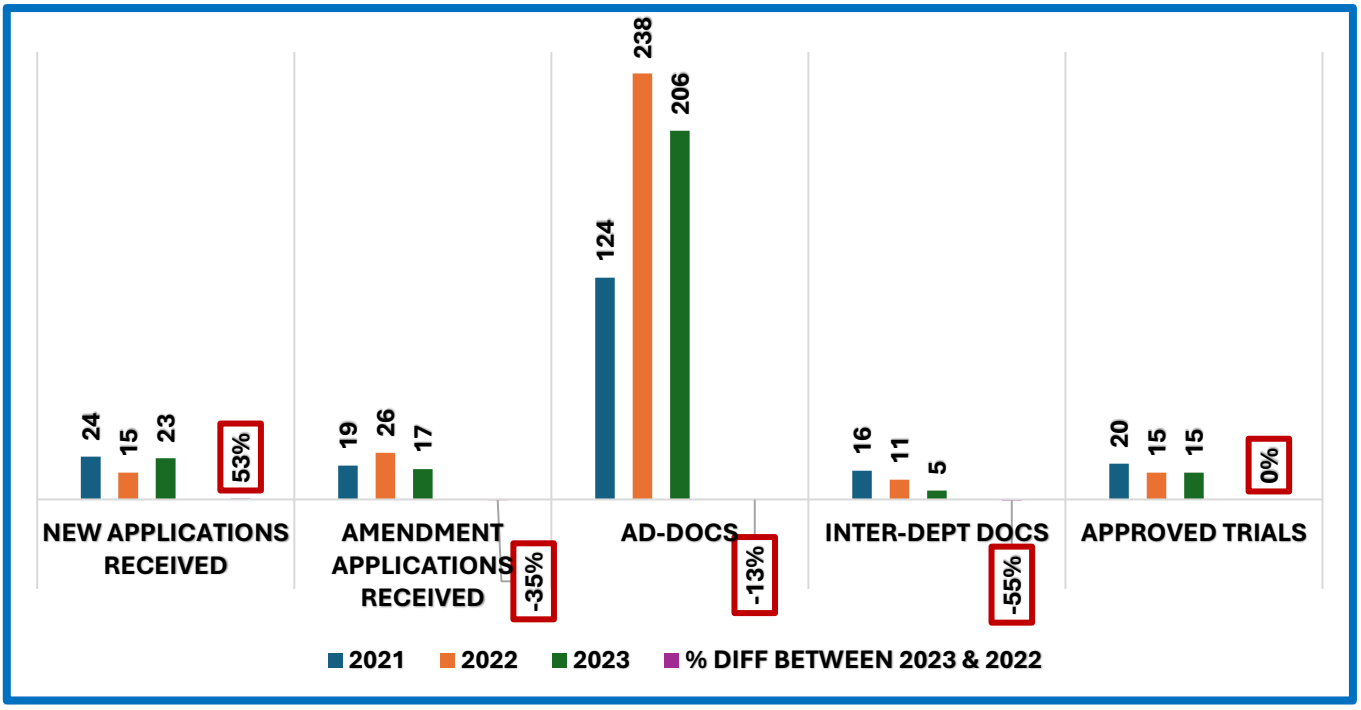
To curb the importation of unregistered products through the Tema Port, the FDA initiated the "zero tolerance" program for the importation of unregistered products. The implementation of the "no registration, no importation " policy at the Tema port in May 2021 has resulted in a cumulative

77% decrease in the detention of unregistered consignments. This reduction has alleviated the workload on enforcement teams, allowing them to redirect their focus towards other critical regulatory tasks.

3.8 Clinical Trial Authorization.

The increase in detention of unregistered products for 2023 is associated with enforcement measures to control the importation of unbranded diaper packaged in bales.

Figure 3.8-1: Trend of clinical trial authorization performance

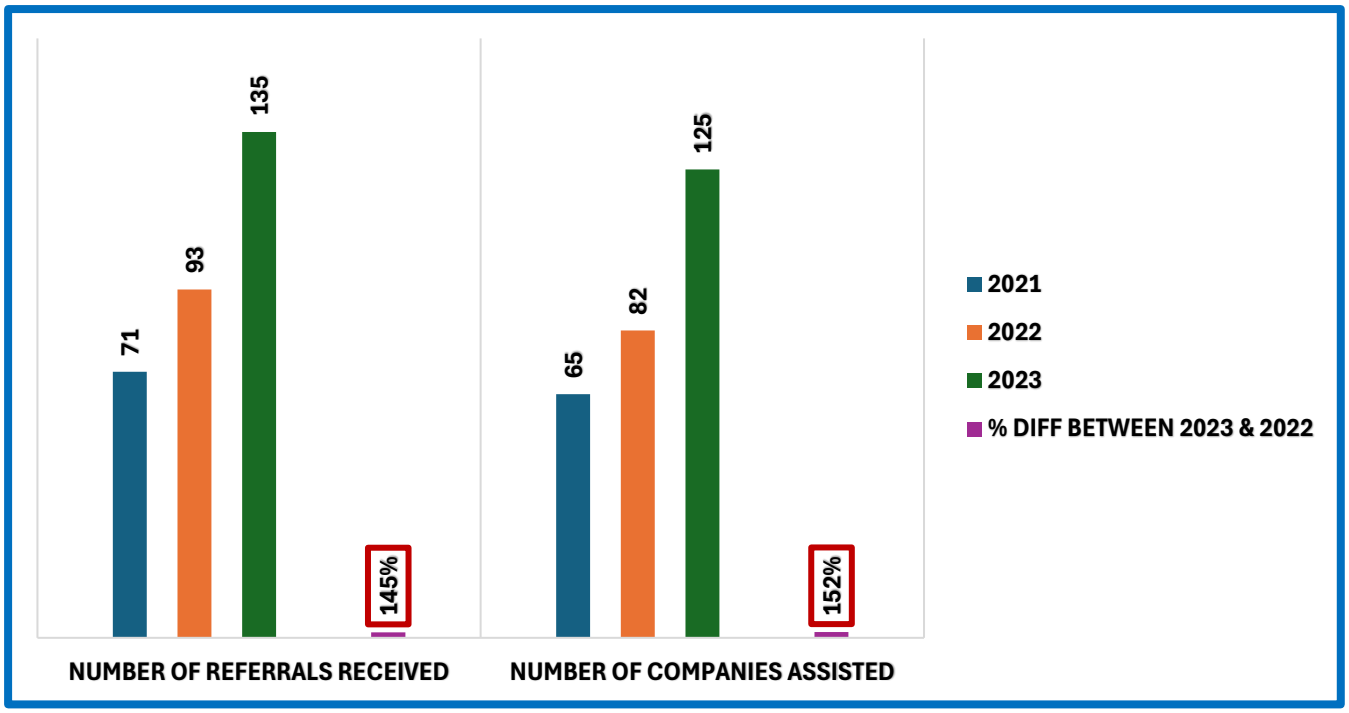


Source: FDA Planning, Monitoring and Evaluation Department (2023)

The number of new applications received and reviewed increased by 53% from 2022 to 2023. There were fewer amendment applications received in 2023 compared to 2022. Additionally, the number of additional clinical trial-related documents submitted, and interdepartmental documents received decreased from 2022 to 2023. Overall, the total submissions made for 2023 decreased. This reduction is attributed to the termination of some studies, primarily Covid-19 studies, due to a lack of study participants. In total, fifteen (15) clinical trial applications were approved in the year 2023.

3.9 Support for Local Industry

3.9.1 Technical support to Industry



***Source**: FDA Planning, Monitoring and Evaluation Department (2023)*

The FDA initially planned to conduct One Hundred and Two (102) technical assistance programs for industries in 2023. However, by the end of the year, One Hundred and Twenty-Five (125) technical assistance programs had been successfully carried out, surpassing the set target by 23%.

Over the course of three years, there has been a notable increase in both the number of referrals received and the companies assisted. In 2023, the number of referrals received reached One Hundred and Thirty-Five (135), a significant increase of 145% compared to the previous year, 2022. Similarly, the number of companies assisted rose to One Hundred and Twenty-Five (125) in 2023, reflecting a remarkable 152% increase from 2022. These substantial rises indicate a growing demand for assistance and support within the industry, showcasing the organization's proactive approach in addressing the needs of companies and facilitating their growth and compliance with regulatory standards.

3.9.2 Capacity Strengthening

3.9.2.1 Training Programmes

In 2023, the annual target for the number of participants trained in Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) was set at 350 for each. However, by the year's end, a total of 371 participants had received training in GMP, achieving 6% above the annual target. Additionally, 641 participants had been trained in GHP, surpassing the target by 83%. In total, 1,012 participants from 260 companies underwent training in various aspects of Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP).

3.10 Tobacco and Substances of Abuse Control

3.10.1 Tobacco Control

The 2023 annual target for the number of tobacco product applications was Twenty-Two (22). By the end of the year, the FDA received all Twenty-Two (22) applications. All received applications were subsequently processed, and Eighteen (18) were approved. Additionally, One Hundred and Thirty (130) permit applications for tobacco products were received, of which One Hundred and Eleven (111) were approved, and Nineteen (19) were rejected.

The reconstitution and strengthening of the Tobacco Control Inter-Agency Coordinating Committee (TC-IACC) aimed to expedite the implementation of WHO Framework Convention on Tobacco Control (FCTC) protocols and bolster multisectoral cooperation. Additionally, a Draft Tobacco Advertising, Promotion, and Sponsorship Enforcement Guide was formulated to delineate stakeholder responsibilities in enforcing the ban on tobacco-related advertising, promotion, and sponsorship in Ghana. The official launch of the National Tobacco Control Strategy (NTCS) provided a structured framework for tobacco control efforts in the country, aligning with provisions of the WHO FCTC and outlining stakeholder engagement over the next five years. A Needs Assessment Mission on the Protocol to Eliminate Illicit Trade in Tobacco Products involved bilateral discussions with various institutions in Ghana, documenting existing needs and challenges to streamline tobacco control measures effectively.

Furthermore, a draft roadmap for the implementation of the Protocol to Eliminate Illicit Trade in Tobacco Products was devised to guide future actions. To enhance understanding and readiness for implementation, training sessions on the Protocol were conducted in the Greater Accra Region and border areas of Western, Upper East, Volta, Bono, Ahafo, and Bono East Regions.

These sessions identified stakeholders' roles and responsibilities, fostering a coordinated approach to protocol implementation.

3.10.2 Controlled Substances Control

Sixty-Eight (68) facilities were scheduled to be visited to monitor compliance with controlled substances regulation. By the end of the year, Seventy-Two facilities had been audited.

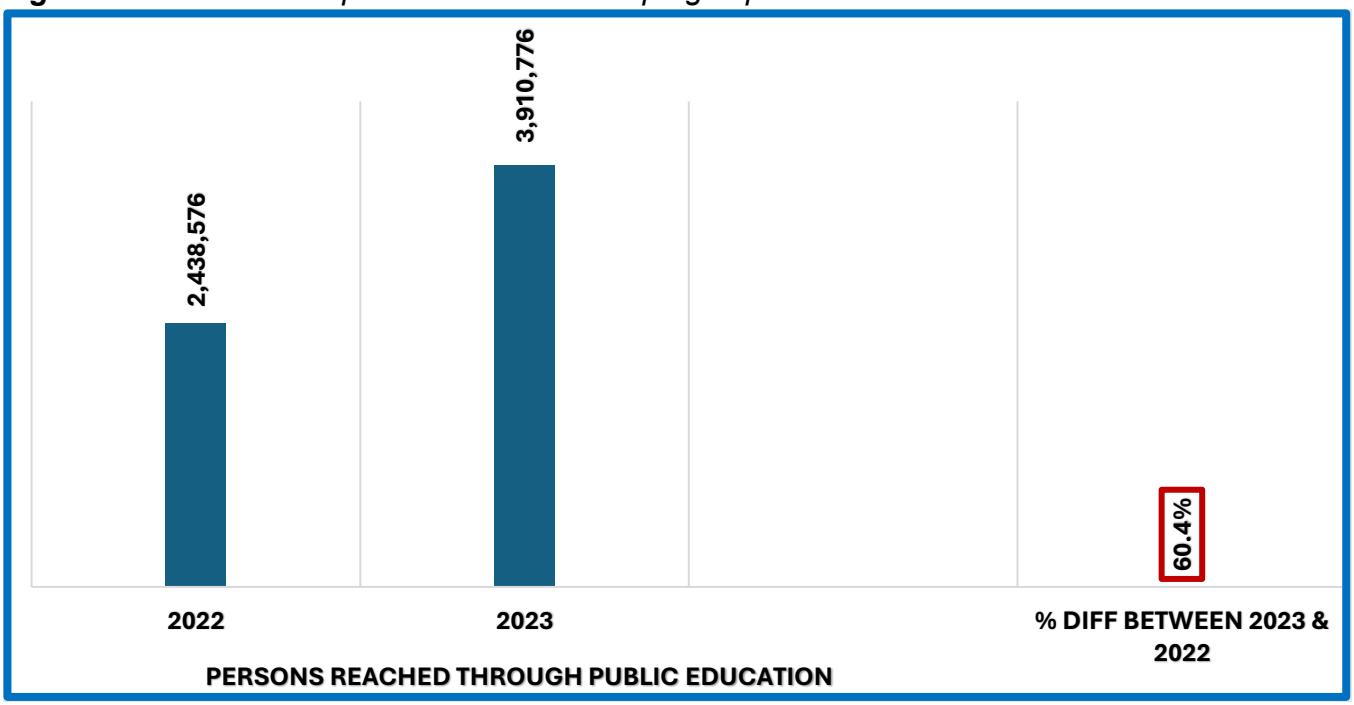
A total of Two Hundred and Sixteen (216) permit applications were received and Two Hundred and Fourteen (214) were vetted for controlled substances. Out of this, One Hundred and Sixty-One (161) permits were issued, Fifty-Three (53) were rejected, and Sixteen (16) import permits were returned. This represents a 5% decrease in permits issued and a 152% decrease in permits rejected compared to the previous year.

The FDA used the Say No to Drug Abuse music video to expand the reach of its message across social media platforms. The video reached a total of Twenty-Six Thousand One Hundred and Ninety-Eight (26,198) individuals through YouTube and One Hundred and Twenty-One Thousand Six Hundred and Eighty-Two (121,682) individuals through other social media channels. Furthermore, there were Fifteen (15) media engagements aimed at promoting the music video and raising awareness about the hazards of substance abuse. The video was also broadcasted in Ninety-Three (93) public locations, including schools, marketplaces, and bus terminals, during public education initiatives.

3.11 Public Awareness and Education

The annual target for the number of persons to be reached with training programs was set at Two Million Six Hundred and Eighty-Two Thousand Four Hundred and Thirty-Three (2,682,433). However, by the end of the year, a total of Three Million Nine Hundred and Ten Thousand Seven Hundred and Seventy-Six (3,910,776) persons had been reached, surpassing the target by 146%.

Figure 3.11-1: *Trend of public education campaigns performance*

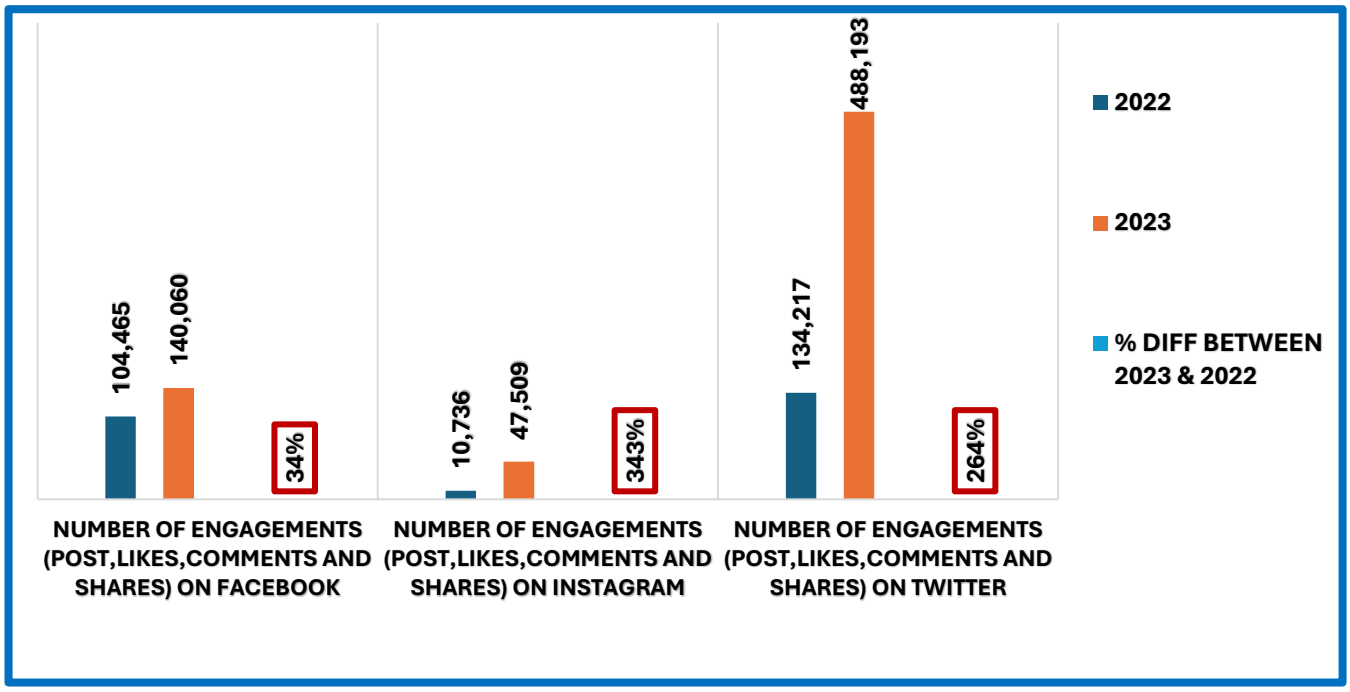


Source: FDA Planning, Monitoring and Evaluation Department (2023)

Educational campaigns were organized for various segments of the population, including basic and secondary schools, tertiary institutions, marketplaces, transport terminals, non-governmental organizations (NGOs), religious organizations, and the media (radio, TV stations, and electronic stations) Public education programmes were centred around food and drug safety.

3.11 Communication and Public Education

The annual target for the number of press releases issued in 2023 was twenty (20), by the end of the year, a total of twenty-nine (29) press releases had been issued, surpassing the target.



Source: FDA Planning, Monitoring and Evaluation Department (2023)

In 2023, online activities demonstrated improvement compared to previous years. There was a notable increase in social media engagements, publications posted on FDA social media handles, and monitored online stories throughout the period. By the end of the year, the total number of social media engagements on Facebook, Twitter, and Instagram reached Six Hundred and Seventy-Five Thousand Seven Hundred and Sixty-Two (675,762), marking a significant increase of 171% compared to engagements from the previous year.

3.12 Donor Funded Projects

During the review year, the institution undertook various activities for donor-funded projects:

No.	Project Name	Details
1	EU – GIZ Joint Action	• Initiated the feasibility study phase for the ISO Class 7 with 8 Background Cleanroom construction. • Finalized tender documentation and signed a construction contract with Paddox. • Organized a hands-on training program for forty (40) FDA staff in quality, clinical, and non-clinical assessment of vaccine dossiers.

		• Procured Videoconferencing equipment, ICT equipment and four servers for IRIMS deployment.
2	Collaboration with Bill and Melinda Gates Foundation (BMGF)	• Completed theoretical and hands-on GCP training for FDA regional officers in Clinical Trials • Completed internal stakeholder training and sensitization for Lot Release Testing.
3	USAID/USP Global Vaccine Project	• Secured funding for the acquisition of IRIMS. • Procured and Installed aboratory testing equipment. • Completed capacity building activities for FDA staff in biomanufacturing in Ghana, including a study visit to India and training in Good Storage and Distribution Practices in Accra. • Completed Independent Lot Release training for FDA staff. • Supported the advocacy for improved safety reporting at the lower-level facilities Clinics, Community-Based Health Planning and Services (CHPS) zones and health centres. • Secured funds and completed design work for the upgrade of FDA's website. • Drafted and finalized Lot Release documents for FDA. • Conducted sample selection for maternal neonatal and child health medicines across Ghana.
4	Implementation of ProPerSeals	• Concluded level 1 processes and rolled out Level 2 ; registered clients and detained non-compliant consignments • Started the pilot test for serialization at Level 3 with select clients. • Created a workflow for the advertisement approval process
5	ECOWAS-Regulators and Ethics Committees (RegECs)	• Organised a roadmap meeting for Work Package 2 of the EDCTP-funded ECOWAS-RegECs Project.

6	Healthier Diet for Healthier Life (HD4HL)	• Collected data on food product labels that aided in policy formulation
7	US Centers for Disease Control/Task Force for Global Health (CDC/TFGH)	**Ghana Infodemic Management (IM) Project** • Conducted IM Training for selected staff from the FDA, Ghana Health Service, EPI by a team of facilitators from the US CDC on Infodemic Management. • Formulated a National Insights team from the trainees. • Generated fmonthly Ghana Infodemic Management Report (GIMIR). • Formed zonal teams across the country. Engaged in the mentorship of members of the Zonal Insights Team. **VRE Plan** • Successfully evaluated the process used for evaluating process and a process in developing the plan.
8	UNICEF	• Supported for the celebration of the 2023 World Breastfeeding Day. • Disseminated findings on the monitoring of the Li 1667, Breastfeeding Code. • Supported for the production and printing of the abridged versions of the Li 1667, Breastfeeding Code.
9	Sub-Delegation Project with AUDA NEPAD	• Identified sentinel facilities through an initial engagement with FDA regional officers. • Developed a training plan and materials for the establishment of the sentinel sites. • Held several virtual Joint Signal Management Group meetings. • Conducted meetings to plan stakeholder as part of the sub-delegation project.

4.0 2023 FINANCIAL PERFORMANCE

The FDA commenced the fiscal year 2023 with a revenue target of One Hundred and Fifty-Three Million, Six Hundred and Sixty-Two Thousand, Seven Hundred and Forty-Four Ghana Cedis, Fifty Pesewas (GH¢153,662,744.50). However, by midyear, this target was revised to One Hundred and Eighty-Three Million, Four Hundred and One Thousand, Eight Hundred and Seventy-Two Ghana Cedis, Seventy-Three Pesewas (GH¢183,401,872.73) to accommodate the Authority's increased expenditure budget. By the year's end, the FDA had collected a total of One Hundred and Eighty-Four Million, Two Hundred and Twenty-Five Thousand, Five Hundred and Sixty-Five Ghana Cedis, Fifty-Two Pesewas (GH¢184,225,565.52). This figure represents a significant increase of 31% compared to the One Hundred and Forty-One Million, Seventy-Eight Thousand, Three Hundred and Sixty-Three Ghana Cedis, Sixty-Four Pesewas (GH¢141,078,363.64) generated in the previous year.

Out of the total revenue collected, Forty-Seven Million, Two Hundred and Thirty-Five Thousand, Six Hundred and Eighty Ghana Cedis, Forty-Four Pesewas (GH¢47,235,680.44) was transferred to the consolidated fund, while One Hundred and Thirty-Six Million, Nine Hundred and Eighty-Nine Thousand, Eight Hundred and Eighty-Five Ghana Cedis, and Eight Pesewas (GH¢136,989,885.08) were allocated to operational activities as detailed below:

***Table** 4.0-1: Revenue Budget and Actual Performance*

2023 ANNUAL BUDGET (GHS)			
	BUDGETED	**ACTUAL**	**VARIANCE**
Total Revenue	183,401,872.73	184,225,565.52	823,692.79
FDA Retention	128,381,310.91	128,957,391.86	576,080.95
Transfer to Consolidated Fund	55,020,561.80	47,235,680.44	(7,784,881.36)

Source: FDA Financial Report (2023)

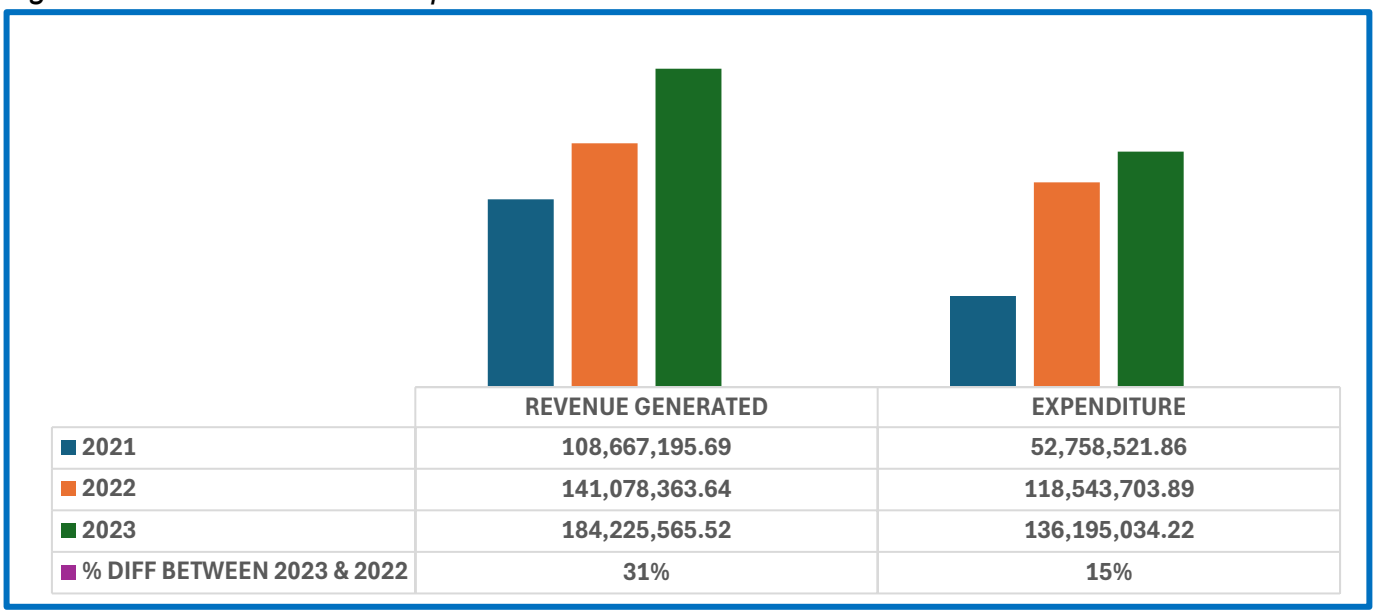
***Table 4.0**-2: Expenditure Budget Performance*

EXPENDITURE ITEMS	**BUDGET(GHS)**	**ACTUAL (GHS)**	**VARIANCE (GHS)**
IGF Compensation	25,651,262.18	25,725,711.98	-74,449.80
Goods & services	77,053,786.55	87,447,943.92	-10,394,157.37
Capital expenditure	25,676,262.18	23,021,378.32	2,654,883.86
Total	128,381,310.91	136,195,034.22	-7,813,723.31

Source: FDA Financial Report (2023)

In 2023, the FDA exceeded the IGF Compensation and Goods and Services budgets by 0.29% and 13%, respectively, as delineated in Table 4.0-2 above. Additionally, there was a 10.34% decrease in the Capital Expenditure budget compared to the allocated amount. The overall expenditure budget for 2023 surpassed its target by 6%, primarily due to general increases in the prices of goods and services, expansion in staff strength, fluctuations in exchange rates, and revisions in previously contracted agreements by the institution.

Figure 4-0-1: Revenue and Expenditure Performance



	REVENUE GENERATED	EXPENDITURE
2021	108,667,195.69	52,758,521.86
2022	141,078,363.64	118,543,703.89
2023	184,225,565.52	136,195,034.22
% DIFF BETWEEN 2023 & 2022	31%	15%

***Source**: FDA Financial Report (2023)*

The Authority targeted to generate One Hundred and Eighty-Three Million, Four Hundred and One Thousand, Eight Hundred and Seventy-Two Ghana Cedis and Seventy-Three Pesewas (GH¢183,401,872.73). However, a total of One Hundred and Eighty-Four Million, Two Hundred and Twenty-Two Thousand, Five Hundred and Sixty-Five Ghana Cedis and Fifty-Two Pesewas (GH¢184,225,565.52) was generated by the end of the year exceeding the target by 0.4% and represented an increased revenue collection by 31% compared with 2022 figures.

The annual budget for expenditure was One Hundred and Twenty-Eight Million, Three Hundred and Eighty-One Thousand, Three Hundred and Ten Ghana Cedis and Ninety-One Pesewas (GH¢128,381,310.91), however, the institution spent One Hundred and Thirty-Six Million, One Hundred and Ninety-Five Thousand and Thirty-Four Ghana Cedis, Twenty-Two Pesewas (GH¢136,195,034.22) exceeding the target by 6% and increased in expenditure by 18%

compared to 2022 expenditure figures due the general increase in the prices of goods and services, increase in exchange rates and upward review of contracts.

4.1 Internal Audit

The Internal Audit Directorate (IAD), in accordance with sections 16 (3&4) of the Internal Audit Agency Act, 2003, and section 83 of the Public Financial Management Act, 2016 (Act 921), submitted an annual audit plan to both management and the audit committee of the board, which was duly approved for the year under review. Pursuant to the 2023 annual audit plan, five (5) financial audits were conducted, revealing four (4) instances of non-compliance. These financial audits covered essential areas including the Head Office, Tema Office, KIA Office, and the nine (9) Regional Offices. The observed non-compliances comprised 75% inadequate documentations and 25% records issues.

Pre-audit and verification activities, focused on pre-expenditure payments and payroll vouching, ensured thorough review of all payments and payroll requests before disbursement. All payments and payroll requests received underwent rigorous processing for compliance. Furthermore, procurement items and supplies to the FDA Stores were meticulously verified, with no exceptions noted during the review period. In terms of performance audits, although the directorate had initially planned four (4) audits, changes in the required man-hour necessitated the execution of five (5) audits. The conducted performance audits contributed to enhanced operational controls within the respective audited units.

5.0 SUMMARY OF KEY ACHIEVEMENTS FOR 2023

The FDA achieved the following in Operation, Regional Operations, Projects, Partnership and Collaborations, Trainings/Educational and Awards

1. **Certification and Accreditations**

    a. The Authority maintained its ISO 9001:2015 certification for technical and administrative functions.

    b. The FDA became the first Regulatory Agency (ahead of WHO) to grant approval to the R21 Malaria vaccine.

    c. The Centre for Laboratory Service and Research has maintained ISO 17025:2017 accreditation for 58 tests.

2. **Capacity Strengthening Hub**

b. The FDA was designated as a Regional Center for Regulatory Excellence for Vaccines Regulatory Oversight in 8 out of 9 functions (except Lab Lot Release) by the AUDA-NEPAD.

c. The FDA Developed RCORE manual to train regulators in the area of market authorization for vaccines and Pharmacovigilance (Vigilance).

e. The FDA hosted a delegation from the Guinean Ministry of Health & Public Hygiene who were on a 2-day benchmarking visit to understand the FDA's legal framework & regulatory best practices for institutional strengthening.

f. FDA Ghana received a four-member team from Rwanda FDA on a benchmarking visit to understudy the processes involved in the regulation of Cosmetics and Household Chemical Substances in Ghana in their bid to strengthen their regulatory processes and structures in their home country.

g. The FDA hosted a 5-member delegation from the Senegalese Pharmaceutical Regulatory Authority (Agence Sénégalaise de Réglémentation Pharmaceutique - ARP) who were on a study visit from Monday, 21st to Friday, 25th August 2023.

h. The FDA hosted a 4-member delegation from the National Drug Regulatory Authority of Mozambique (ANARME) from Monday, 28th August 2023, to Friday, 8th September 2023.

i. An 11-member delegation from the South African Health Products Regulatory Authority (SAHPRA), University of Free State as well as the Department of Science and Innovation all from South Africa visited the FDA to understudy the regulation of herbal medicines in Ghana.

j. The Authority Hosted the 4 Technical staff and 8 Board Members from Botswana Medicines Regulatory Authority (BOMRA) on a four-day and 5-day study tour respectively.

3. **Regional Operations**

a. Operationalization of the regional office at Nalerigu in the North-East Region.

b. Operationalized border post at Sampa in Bono Region and Bungrugu border post in Northeast Region.

d. The Central Region received two awards from the Central Regional Coordinating Council for being one of the most professional exhibitors and the exhibitor with the most educative materials during the Central Expo 2023 which took place in Cape Coast.

4. **Projects**

a. The construction of the road in front of FDA Heights, Tema was completed.

b. Completion of renovation of Laboratory at Head Office.

5. **Partnership and Collaborations**

a. The Maiden Annual Stakeholders Meeting (ASM) to update stakeholders on our regulatory activities and achievements for 2022 was held successfully.

b. Maiden Scientific Forum on the theme: 'Protecting Public Health and Safety through Partnership (with Industry and Academia) was organized. Successfully.

c. A 5-year National Tobacco Control Strategy to strengthen multisectoral cooperation was launched successfully.

6.0 Staff Trainings/Educational Achievements

a. Eight (8) staff participated in a hands-on training program on Good Manufacturing Practices in Vaccine Manufacturing at the Biotech Training Facility in Leiden, Netherlands.

b. Forty (40) staff participated in a hands-on training in quality, clinical and non-clinical assessment of vaccine dossiers organized by Phareg Consult in Accra.

c. Eight (8) Staff completed Masters programme. Eight 8) staff sponsored; 1 PhD and 7 Masters.

7.0 Stakeholder Capacity Strengthening

a. The FDA trained law enforcement agencies throughout the country on the Protocol to Eliminate Illicit Trade in Tobacco Products, to build technical

capacity, enhance collaboration, and create awareness on the Protocol at the various sub-national levels emphasizing the multifaceted approach to the global threat of illicit tobacco trade.

b. Importers and manufacturers of controlled substances (CS) were trained on emergence of new psychoactive substances such as synthetic opioids and cannabinoids, and current regulatory requirements, to ensure Ghana's continuous compliance to the 3 UN Drug Conventions.

c. There was a significant increase in the number of stakeholders trained (534) in GCP - close to 100% increase from previous years.

d. A total of one hundred and sixteen (116) Micro/Small and Medium Enterprises (MSME's) were trained during the period under review.

e. The Monitoring and Evaluation Department hosted seven (7) officers from the Ghana Water Company Limited for an internship programme which started on the 20th of November and ended on the 8th of December. These interns were taken through the basic rudiments of Planning, Monitoring and Evaluation and Budgeting for their internship.

f. The FDA in collaboration with the Komfo Anokye Teaching Hospiital organized a workshop for health workers targeted at optimizing patient care through rational drug use.

8.0 Technology and Digitisation

a. Phase 1 of the implementation of the integrated Regulatory Information Management Systems (iRIMS) to fully digitize and integrate our regulatory functions and related support functions was completed.

b. Approval app for the Smart Workplace was deployed.

c. Detention Management and Monitoring System for CIEC Deployed

d. Deployment of the Enforcement Management and Monitoring System for the Operations, Intelligence and Investigation Departments under the Enforcement Directorate

9.0 Research and Publications

a. The CLSR developed a new method for testing Sudan dyes in palm oil at 100 ppb, an improvement over the previous limit of 400 ppb)

b. A Full research paper was published in the Sage Digital Health Journal & 3 posters/1 oral presentation

c. The 22nd International Society of Pharmacovigilance Conference was held in Bali Eight (8) research articles have been completed for publication in addition to other 18 poster presentations.

10.0 Awards

a. The Authority won the Overall specified **Entity of the Year**, **OSE of the Year** and the **Best OSE - Dynamic Effect** awards at the 2023 Public Enterprise League Table Awards.

b. FDA Ghana was awarded the 'Most Effective Public Sector Organization' in the Central Region during the Osabarima Royal Awards program.

c. FDA Ghana, along with its Head of Communication and Public Education Department, Mrs Rhoda Ewurabena Appiah, honored as one of the Top 20 Brand Public Sector Institutions in Ghana and the Brand Communication Personality of the Year 2022 respectively.

d. Mrs. Akua Amponsaa Owusu, the Bono Regional Head of the Food and Drugs Authority, received an award for the Most Outstanding Institutional Head in the Ahafo Region.

e. CEO, Dr. Delese Darko was recognized for her distinguished leadership at the Ghana Pharma and Healthcare awards. She received an outstanding Leadership Award (female category) at the event held yesterday at Kempinski Hotel, Accra Corporate.

f. CEO, Dr. Delese Darko received an award for Outstanding Public Service - Female Personality of the year, at the 13th edition of the Ghana Entrepreneurs and Corporate Executives Awards and Summit, 2023 ceremony.

g. National Honors conferred on the Authority and Chief Executive Officer, at a special awards ceremony in recognition of the remarkable and selfless services in the fight to contain the COVID-19 virus.

h. The CEO of the FDA, Mrs. Delese Mimi Darko was given the Scientific Conference on Medical Products Regulation in Africa (SCOMRA) Award during the year under review.

i. CEO of the FDA being a member of the National Covid-19 Task Force was awarded Order of the Volta- Companion by the President of the Republic.

11.0. CHALLENGES AND MITIGATING STRATEGIES

CHALLENGE	EFFECT	MITIGATION MEASURE
Unapproved and/or unmanned border posts.	**>38,105** non-compliant products were detained in 2023.	Intelligence driven swoops
Consolidated consignments cleared at Tema Port.		100% consolidated consignment inspection.
Personal luggage and courier packages at KIA.		Securing necessary approvals to establish FDA posts at KIA:
Absence of a module for processing exports on the ICUMS.	Export of regulated Products without FDA documentation.	Engagement with Customs and Ghana Link for development of export process on ICUMS.
	FDA receives safety alerts on consignments exported with FDA approval.	Creating stakeholder awareness.
Inadequate vehicles for Inspections	4,918 inspections were not carried out >15,000 facilities across the country not regulated by the FDA.	The use of ride hailing services.
	Long inspection waiting time: 2 – 5 months for food service establishments. Up to 1 month for manufacturing & storage facilities.	Active surveillance for unlicensed facilities. Risk-based inspection scheduling and planning.
Obsolete and lack of key lab equipment	The 8 – 20-year-old equipment are expensive to maintain. Replacement parts not available. Require >GHS60 million to retool the lab. Palm oil consignment re-exported to Ghana by EU border control.	Solicit donor support

Uncompetitive renumeration, conditions of service and pension	>40 highly trained and experienced staff have resigned within the last 5 years. it is extremely difficult to replace such key staff. Staff exposed to being compromised.	Implemented new organogram. Negotiating revised conditions of service with Fair Wages and Salaries Commission.
Inadequate staff for operational activities	Increased backlog of inspections. Fewer retail outlets are inspected. Inability to undertake scouting for new facilities.	National service personnel Applied for financial clearance for recruitment.

12.0 PRIORITIES AND OUTLOOK FOR 2024

Accreditations

- To maintain WHO GBT ML3 and achieve ML4 status.

Digitisation of Operational Activities

The FDA will implement the following systems:

- Full implementation of integrated Regulatory Information Management System (IRIMS) by May 2024; system was deployed in November,2023.
- Upgrade of Laboratory Information Management System (LIMS) by June 2024; contract signed in November, 2023.
- Achieving Levels 3 & 4 of ProPer Seals Platform - a track and trace system to enhance product security and supply chain integrity.
- Continue automation of workflows using the GoG Smart Workplace Platform for administrative and operational work processes.

Projects

- Construction of Fence Wall around the FDA Land in Northern Region and Upper West Region and Western North Region.
- Construction of 3-Storey Office Complex for the FDA in the Volta Region.
- Construction of additional Works at FDA Heights in Tema.
- Reconstruction of Official Residence for Northern Regional Head, Tamale.
- Construction of ISO Class 7 and 8 Clean Room at the FDA Head Office.
- Refurbishment of space for molecular biology laboratory at FDA Heights.
- Renovation of Food Lab near the TUC office – electrical and plumbing works
- Procurement of ICT equipment

Staff Remuneration

- Secure approval for revised staff conditions of service
- Pursue 100% retention of IGF from Government
- Explore other new salary structure other than the single spine.

Partnerships and International Collaborations

The FDA will solicit funding for the following:

- Regulatory systems strengthening for local vaccine manufacturing.
- Strengthening regulatory support for sustainable growth of micro and small-scale industries.
- Capacity building initiatives for FDA staff
- Acquisition of equipment to support overall regulatory capabilities across FDA operations.

13.0 WAY FORWARD

Product registration targets for applications received are a combination of new and renewal applications; both are dependent on applicant decisions to submit application. Strengthening enforcement activities in the markets, seaports, airports, and border posts will contribute to an increase in applications submitted for products registration as well as facility licensing. The FDA is in the process of developing an online systems and strategies which will alert FDA of registered products due for reregistration but are still on the Ghanaian market.

The FDA will deploy additional manpower and resources to support surveillance, inspections, public education, monitoring, and enforcement activities. National service personnel have been

key to our performance for the past couple of years, and therefore with the deployment of the additional manpower of the national service persons done, it is believed it will go a long way to close the gaps in the FDA's operational areas.

14.0 APPENDICES
APPENDIX I – LIST OF GOVERNING BOARD MEMBERS

FDA GOVERNING BOARD MEMBERS				
S/N	**NAME**	**INSTITUTION**	**POSITION IN INSTITUTION**	**POSITIONON THE BOARD**
1	Dr. Sammy Ohene	University of Ghana Medical School	Head of Psychiatry Department	Chairman
2	Dr. Delese A. A. Darko	Food and Drugs Authority	Chief Executive Officer	Member
3	Dr. Audu Rauf	Pharmacy Council	Registrar	Member
4	Professor Alex Asase	Centre for Plant Medicine and Research	Executive Director	Member
5	Prof. Charles Tortoe	CSIR- Food Research Institute	Acting Executive Director, CSIR-Food Research Institute	Member
6	Dr. Joyce Dontwi	Veterinary Services Directorate	Director	Member
7	Nana. K. Obiri	Ghana Federation of Traditional Medicine Practitioners Ass Medicine Practitioners Association (GHAFTRAM)	National Organizer	Member
8	Dr. Alhassan Emil Abdulai	University of Ghana. Accra.	Senior lecturer & Head of Departmental and Maxillo-Facial Surgery, School of Medicine & Dentistry	Member
9	Mrs. Martha Osei	Communication for Development Centre	CEO, Communication for Development Centre	Member
10	Prof. Alexander Dodoo	Ghana Standards Authority	Executive Director	Member
11	Mrs. Anna Pearl Akiwumi-Siriboe	Ministry of Justice and Attorney General's Department	Chief State Attorney	Member
12	Mrs. Yvonne Nkrumah	Food and Drugs Authority	Deputy Chief Executive Officer	Board Secretary

APPENDIX II – LIST OF EXECUTIVE COMMITTEE MEMBERS

EXECUTIVE COMMITTEE MEMBERS				
S/N	**NAME**	**DIVISION/CENTRE/DIRECTORATE**	**POSITION IN DIVISION/DIRECTORATE**	**POSITION ON STRATEGIC MANAGEMENT**
1	Dr. Delese A. A. Darko		Chief Executive Officer	Chairman
2	Mr. Seth K. Seaneke	Health Products & Technologies Division	Deputy Chief Executive Officer	Member
3	Dr. Akua O. Amartey	Technical Operations Division	Deputy Chief Executive Officer	Member
4	Mrs. Yvonne Nkrumah	Corporate Services Division	Deputy Chief Executive Officer	Member
5	Mr. Roderick Daddey Adjei	Food Division	Deputy Chief Executive Officer	Member
6	Mr. Eric Karikari-Boateng	Centre for Laboratory Services and Research	Director	Member
7	Mr. Percy Adomako	Centre for Import & Export Control	Director	Member
8	Mr. Nicholas Agbomadzi	Finance Directorate	Director	Member
9.	Mr. Edem Kofi Kugbey	Internal Audit Directorate	Director	Member
10	Mr. Joseph Yaw-Bernie Bennie	Legal and Corporate Affairs Directorate	Director	Member
11	Mr. Kwame Dei Asamoah Okyere	Business Development & International Partnership Directorate	Director	Secretary

APPENDIX III – LIST OF MIDDLE LEVEL MANAGEMENT (MLM)

DIRECTORS/REGIONAL HEADS				
S/N	**NAME**	**DIRECTORATE/REGION/DEPARTMENT**	**POSITION**	**POSITION ON MLM**
1	Mr. Joseph Bernie Bennie	Legal and Corporate Services Directorate	Director	Chairman

2	Mrs. Faustina Atupra	Food Safety and Consumer Education Directorate	Director	Member
3	Mr. Vigil Eshun Prah	Enforcement Directorate	Director	Member
4	Ms. Maria Lovelace-Johnson	Inspectorate Directorate	Director	Member
5	Mr. Ebenezer Kofi Essel	Industrial Support Services Directorate	Director	Member
6	Ms. Nora Narkie Terlabie	Regional Operations Directorate	Director	Member
7	Mr. Samuel Asante Boateng	Drug and Herbal Medicine Registration Directorate	Director	Member
8	Mr. Emmanuel Nkrumah	Medical Devices, Cosmetics and Household Chemicals Directorate	Director	Member
9	Dr. Edwin Nkansah	Clinical Trials and Safety Monitoring Directorate	Director	Member
10	Mr. James Y. Lartey	Administration Directorate	Director	Member
11	Dr. Mrs. Olivia Agyekumwaa Boateng	Tobacco and Substances of Abuse Directorate	Director	Member
12	Mrs. Maureen Lartey	Food Registration and Applied Nutrition Directorate	Director	Member
13	Kwame Dei Asamoah Okyere	Business Development and International Partnership Directorate	Director	Member
15	Ms. Francisca Obeng	Central Regional Office	Ag. Regional Head	Member
16	Mr. Gorden Akurugu	Volta Regional Office	Regional Head	Member
17	Dr. Martin Kusi	Western Regional Office	Regional Head	Member
18	Mr. John Odai Tettey	Ashanti Region	Regional Head	Member
19	Ms. Akua Amponsaa Owusu-Antwi	Bono Regional Office	Regional Head	Member
20	Ms. Anita Kuffour	Eastern Regional Office	Ag. Regional Head	Member
21	Mr. Albert Ankomah	Western North Regional Office	Regional Head	Member
22	Mr. Zackariah Braimah	Northern Regional Office	Regional Head	Member

23	Mr. Sebastian Hotor	Upper East Regional Office	Regional Head	Member
24	Mr. Kelvin Dafaari Sunkpal	Upper West Regional Office	Ag. Regional Head	Member
25.	Jacob Amoako Mensah	Northeast Regional Office	Regional Head	Member
26	Mrs. Naana Afrakoma Yawson	Supply Chain Department	Head of Department	Member
27	Mr. Prince Oduro	Financial Audit and Compliance	Head of Department	Member
28	Mrs. Gloria Asum - Kwarteng	Export Control Department	Head of Department	Member
29	Mrs. Harriet Ofori Antwi	Microbiology Laboratory Department	Head of Department	Member/ Secretary
30	Samuel Adom Siaw	Expenditure Department	Head of Department	Member
31	William Agbavitor	Legal Department	Head of Department	Member

APPENDIX IV – LIST OF HEADS OF DEPARTMENTS

DEPARTMENTS			
S/N	**NAME**	**DEPARTMENT**	**POSITION**
1	Jane Amissah Tetteh	Import Control	Head of Department
2	Gloria Asum-Kwarteng	Export Control	Head of Department
3	Nana Afrakoma Ashia	Data Management	Head of Department
4	Marian Kommey	Food Laboratory	Head of Department
5	Patrick Owusu-Danso	Drug Laboratory	Head of Department
6	Frederica Liz Hayford	Veterinary	Head of Department
7	Harriet Ofori-Antwi	Microbiology	Head of Department
8	Ishmael Larkai	Medical Devices	Head of Department
9	Prince Oduro	Financial Audit and Compliance	Head of Department

10	Emmanuel Aguedzi Tetteh	Revenue	Head of Department
11	Samuel Adom Siaw	Expenditure & Reporting	Head of Department
12	Nana Serwah Boateng	Strategy, Partnerships & International Collaboration	Head of Department
13	Joseph Ofosu Siaw	Quality Management System	Head of Department
14	Afua Amoako-Mensah	Planning, Monitoring and Evaluation	Head of Department
15	Mercy A. Owusu-Asante	Technical Support	Head of Department
16	Abu Sumaila	Capacity Strengthening	Head of Department
17	Jennifer Bonnah	Intelligence	Head of Department
18	Daniel Teye	Operations	Head of Department
19	Mathew Gyan Nkum	Investigations	Head of Department
20	Geoffrey Victor Arthur	Manufacturing Facilities	Head of Department
21	Yvonne Miguela Osei	Storage Facilities	Head of Department
22	Alberta Oduro- Yeboah	Career Development	Ag. Head of Department
23	Alberta Odonkor	Staff Welfare	Ag. Head of Department
24	Pascal Fosu	Administration	Head of Department
25	Naana Afrakoma Yawson	Supply Chain	Head of Department
26	William Korbla Agbavitor, Esq	Legal	Head of Department
27	Rhoda E. Appiah	Communication & Public Education	Head of Department
28	Isaac Marful Dapaah	Information Management & Technology Solutions	Head of Department
29	Eric Owusu	Drugs & Nutraceuticals	Head of Department
30	Ernest Afesey	Herbal & Homeopathic medicine	Head of Department
31	Roland Sefakor	Medical Devices	Head of Department

32	Victor Ofori Antwi	Cosmetics & Household Chemical Substance	Head of Department
33	George Tsey Sabblah	Safety Monitoring	Head of Department
34	Yvonne Ayongo Adu Boahen	Clinical Trial	Head of Department
35	Nathaniel Nkrumah	Vaccines and Biological Products	Head of Department
36	Adah Allotey Pappoe	Substances of Abuse	Head of Department
37	Jemima Donkor	Tobacco and Tobacco Products	Head of Department
38	Percy Adomako	Food Evaluation and Registration	Head of Department
39	Cheetham Mingle	Applied Research and Nutrition	Head of Department
40	Wilhemina Nyanta Quarcoopome	Food Service Establishment	Head of Department
41	Jocelyn Adeline Naa Koshie Egyakwa Amusah	Food Safety Coordination & Consumer Education	Head of Department
42	Barbara Hoffman	Satellite Laboratory Department	Head of Department