FOOD AND DRUGS AUTHORITY

2021 ANNUAL REPORT

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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 2021.

Product Registration

The FDA in 2021 received a total of twenty thousand, eight hundred seventy (20,870) product registration applications; this represents an increase of 13% from the previous year. Out of which a total of seventeen thousand, nine hundred and nine (17,909) products were registered as compared to fifteen thousand, eight hundred and twenty-four (15,824) in 2020; representing an increase of 13% over the previous year; out of this number 65% were foreign products, and 35% local products.

Facility Licensing

The number of applications received increased from four thousand one hundred and five (4,105) to five thousand, and twenty-two (5,022). Out of the applications received, four thousand five hundred and sixty-nine (4,569) licensing inspections were conducted, which is a 37% increase over the 2020 performance. Three thousand three hundred and ninety-nine (3,399) facilities were licensed in 2021, a 34% increase compared to the 2020 performances. A total of seven thousand, nine hundred and thirteen (7,913) inspections were conducted in 2021.

Market Surveillance

In 2021 a total of one thousand, three hundred and twenty-four (1,324) market surveillance operations were carried out across the country; an increase of 73% over the previous year's performance. The number of outlets visited increased by 84% recording fifteen thousand, one hundred and thirty-five (15,135) outlets. The number of non-compliant products was recorded at twenty-two thousand, one hundred thirty-five (22,135) during surveillance, a 37% increase over the previous year.

Product Quality Testing

Six thousand and thirty-nine products (6,039) were received by the lab for testing; a decrease of 13.9% compared to the previous year. Five thousand, four hundred and nine (5,409) products were tested; a decrease of 15.7% over the previous year's performance. Three thousand eight hundred and thirty-nine (3,839) products passed whilst one thousand four hundred and eighty-four (1,484) products failed. The decrease in the number of requests and consequent analysis conducted for 2021 is attributed to a decline in COVID-19 related products that were received for the previous year.

Safety Monitoring of Medical Products

The FDA received ten thousand two hundred and fourteen (10,214) Individual Case Study Reports (ICSR), representing an increase of 236% from 2020. Five thousand one hundred and ninety-one (5,191) were entered into the safety watch system 2021, which included ICSRs received in 2021 and carry overs from the previous period. One thousand two hundred and thirty-six (1,236) reports were submitted to the Technical Advisory Committee (TAC); all ADR submitted to the TAC were reviewed.

Food Safety Surveillance & Investigation

The FDA received parliamentary approval for the Food Safety Policy and also celebrated the World Food Safety Day with a social media interaction of two thousand, two hundred and ninety-one (2291) during the year under review.

As part of the implementation of the National Food Safety Emergency Response Plan, twenty (20) Rapid Response Teams were formed, and sixty (60) officers trained following the adoption and signing of the Food Safety Emergency Response Plan (FoSERP). With assistance from FAO, the FDA conducted a feasibility assessment for the implementation of an e-notification system for food safety issues for both local and imported food commodities in Ghana using the "FAO Technical Guidance for the implementation of e-notification systems for food safety"

The number of food-borne disease outbreaks recorded was five (5), which was the same number/figure as the previous year. There was no death associated with the outbreaks recorded in 2021. The third edition of the Integrated Disease Surveillance and Response System (IDSR) has been published for implementation. This will facilitate reporting and receipt of data from health facilities on food borne diseases.

Import and Export Control

Out of forty thousand, three hundred and sixty- three (40,363) permit applications received, thirty-nine thousand and ninety-nine (39,099) were processed, representing an increase of 15% from the previous year. Thirty-five thousand, two hundred and twenty- four (35,224) permits were issued in 2021, this represented an increase of 20% of permits issued in 2021. The number of import and export consignments inspected decreased by 1% compared to the previous year. This is due to the risk engine in operation at the MPS terminal, which determines which consignment must be inspected largely based on customs' compliance parameters.

Clinical Trial Authorization

The Clinical Trials Department received a total of twenty-four (24) new clinical trial applications, nineteen (19) amendment and one hundred and twenty-four (124) Ad-Doc applications for consideration; (20) twenty out of the twenty-four (24) new applications were approved in 2021. Two hundred and forty-one (241) Serious Adverse Events (SAE) reports were received; nine (9) GCP inspections were conducted in the year 2021 under review; 40% of non-compliances observed were minor, 58% percent were major, and 3% critical non-compliances were observed. A total of forty-one (41) permits were issued for importation of investigational products out of sixty-three (63) applications.

Support for Local Industry (Pharmaceutical)

As a result of the Ghana 2020 GMP Compliance Roadmap, a total of twenty-six (26) pharmaceutical companies out of thirty (30) companies are either building new facilities or renovating pre-existing facilities to GMP compliance. As at the end of the roadmap, none of the facilities had been upgraded to Grade A, whiles there were 27 Grade B and 3 Grade C facilities.

Out of the twenty-five (25) CAPAs relating to the Ghana UNIDO GMP Roadmap which were received and reviewed in 2020, the remaining fourteen (14) verification exercises from 2020 were carried out in 2021.

Support for Local Industry (Food industry)

A total of Four Hundred and Sixty (460) participants from One Hundred and Seventy-four (174) Food Processing Companies were trained in various aspects of Good Manufacturing Practices (GMP) compared to two previous years, which recorded Two Hundred and Ninety-Eight (298) participants in 2019 and Two Hundred and Eighty-One (281) participants in 2020 exceeding the Four Hundred (400) participants target for 2021.

Two Hundred and Two (202) staff from Twenty- Four (24) Food Service Establishments were trained in Food Safety and Hygienic Practices (GHP) exceeding the One Hundred and Ninety (190) participants in 2019 and Three Hundred and Twenty- Six (326) participants in 2020, performance in 2021 saw a decrease in requests made by clients for training. The target for 2021 was Four Hundred (400) participants hence not achieving the target due to the low number of requests received.

Needs Assessments

Ninety (90) Needs Assessments were carried out in different food processing exceeding its annual target of forty (40).

Tobacco and Controlled Substances Control

Seventeen (17) applications were received for registration of tobacco and tobacco products. Fourteen (14) were approved. There was a 13% increase in applications received as compared to the previous year. The department received 121 permit applications for tobacco products. One hundred and seventeen (117) permits were approved and four (4) rejected. There was a 31% increase in permits issued over the previous year.

Controlled substances were issued to twenty-seven (27) importers of raw materials and thirty-two (32) importers of finished pharmaceutical products (FPP). There was a 31% increase in allocation compared to the previous year.

The department received two hundred and eleven (211) permit requests for controlled substances. One hundred and sixty-eight (168) permits were issued, forty-three (43) were rejected and seven (7) import permits were returned. There was a 14% increase in permits issued over the previous year because most of the importers put in an application each for the different controlled substance imported. There was a 7% decrease in import permit applications rejected. Seven (7) import permits were returned since the suppliers of the controlled substances were not able to supply the products to the importers.

Public Awareness and Education

One hundred and two (102) educational campaigns were organized for basic and secondary schools, tertiary institutions, marketplaces, transport terminals, non-governmental organizations, religious organizations and the media (radio, TV stations and electronic stations) which represented 137% increase compared to previous year

Finance

A total of one hundred and eight million, six hundred and sixty-seven, one hundred and ninety-five thousand and sixty-nine pesewas (GH₵ 108,667,195.69) was collected in 2021, an increase of 128% compared to the revenue collected during the previous year. Thirty-seven million, nine hundred and sixty-one thousand, nine hundred and eighty-nine and forty-one pesewas (GH₵ 37,961,989.41) was transferred to the consolidated fund. Fifty-two million, seven hundred and fifty-eight thousand, five hundred and twenty-one and eighty-six pesewas. four hundred and twenty-four thousand, four hundred and sixty-three Ghana Cedis and three pesewas (GH ₵ 52,758,521.86) was spent on operations.

Internal Audit

The internal audit conducted five financial audits, out of these audits, twelve non-compliances were observed by the department. The institution has recorded 100% lodgment for the past 3 years. In 2021, they executed all required financial (revenue and expenditure) audits; this included the Head Office, Tema and KIA Offices, and the nine (9) Regional Offices.

All requests received for review of payrolls, payment vouchers and verification of goods supplied to the FDA stores were completed.

For the period under review, there was no infraction recorded for revenue and expenditure. On payroll audit, there were no infractions observed for promotion updates, annual increments and presence of resigned staff on payroll. This is a tremendous improvement for the organization and demonstrates the impact of effective internal audits on continuous improvement.

Conclusion

In spite of the challenges presented by the COVID-19 pandemic, the FDA largely met its targets and hence had increased performance compared to the same period in 2020. Improvements in performance indicates that our performance will increase operationally and financially as the effects of the COVID-19 pandemic on businesses wanes.

The FDA will continue to evolve to overcome any shocks arising from the COVID-19 pandemic. Technology will be a major driver of improvements in our internal processes to enhance operational effectiveness and efficiency.

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 protect public health and safety through the implementation of regulations for food, allopathic, herbal and veterinary medicines, biological products, medical devices, cosmetics, household chemical substances, clinical trials, tobacco, tobacco products and substances of abuse. The FDA has evolved over the years in response to emerging threats to public health and safety, as well as technologies in product development and manufacturing.

The Food and Drugs Authority (FDA) continues to improve its internal processes in a bid to protect the health and safety of people in Ghana and be a global center of excellence for food and medical product regulation. The results of the 2021 client satisfaction and public confidence survey conducted in the first quarter of 2022, showed a customer satisfaction index of 86% and Pubic Confidence Index of that 83%. As an institution, we continue to deepen our work culture through our core values of accountability, teamwork and integrity to improve the level of confidence our clients and the public have in the agency.

As an organisation we are poised to improve this level of satisfaction of our clients and consumers by deepening our work culture and conscientiously living up to our core values.

The activities of the Authority in its core operational activities of product registration, facility inspections, market surveillance, and safety monitoring; collaboration with other agencies and organizations to provide support, particularly to the Micro, Small and Medium Scale Enterprises (MSMEs); facilitated trade by providing regulatory support to exporters through the National Coordinating Office of the African Continental Free trade Area,; implementation of various flagship initiatives such as Street Vended Food Permit (SVFP), Take Back Unwanted Medicines (TBUM), Progressive Licensing Scheme (PLS), No Registration No Importation and Buy Ghana Love Ghana, support for government of Ghana flagship initiative such as the One District, One Factory (1D1F), The National Entrepreneurship & Innovation Programme (NEIP) and the Nation Builders Corp (NABCO); and FDA-GSA harmonisation plan to reduce bottle necks associated with interactions with both agencies was strengthened in the year under review.

The FDA exploited information communication technology in its operations; an online product registration system to enable clients submit and follow on their applications for product registration from the comfort of their offices was launched and implemented for processing food product applications causing an increase in operational efficiency for the Food Evaluation and Registration Department and all Regional Offices of the Authority.

The FDA with the GOG smart workplace has commenced automation of workflow for memos, leave management, procurement, and finance. This has reduced FDA's carbon footprint in line with Government of Ghana's Climate Policy and enabled staff work out of office to enhance the efficiency of our operations particularly at a time when COVID-19 pandemic changing the face of work; A new certificate software has been developed with enhanced security features to allow authentication of issued certificates by consumers on the FDA website.

The FDA evolved during the turbulent times of the COVID-19 pandemic. Innovations and technology such as working from home, desktop audits and consignment-based testing in place of foreign GMP, personal protective equipment for inspectors, and the implementation of infection prevention control measures were implemented to ensure public health and safety, increased performance and effectiveness.

As part of the national response to combat COVID-19 in Ghana, the FDA employed the emergency use authorisation guidelines and requirements to reduce the processing times for COVID-19 related FDA regulated products, approved six (6) COVID-19 vaccines namely, Sputnik V (Gam-COVID-Vac), CovishieldTM (Oxford/AstraZeneca formulation), COVID-19 Vaccine Janssen (Ad26.COV2. S), Pfizer – BioNTech's Comirnaty (BNT162B2) Moderna's Spikevax (mRNA 1273) Vaxzevira (previously COVID-19 Vaccine AstraZeneca) (AZD1222), inspected and released 20.2 million doses of COVID-19 vaccines for use in the country, set-up a Joint Covid-19 Vaccine Safety Review (JCVSRC) to assess adverse effects following COVID-19 vaccination, established a Safety Monitoring Call Centre to receive adverse effects reports following COVID-19 vaccine deployment and monitors the performance of equipment at the KIA COVID-19 Testing Centre. Confidence in KIA COVID-19 Testing Centre and continual operation of KIA Terminal 3 have contributed to Ghana's international classification as Amber. The first clinical trial for herbal medicine, Nibima, for the treatment of COVID-19 has also been approved.

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 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. Carryout 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 2021.

2.0 MANAGEMENT AND STRUCTURE OF FDA

FDA Governing Board

Martha Rosemond Osei, the President's nominee on the 6th Governing Board of the FDA was appointed as a member on the 16th of September 2021. See appendix 1 for updated membership list of the 6th Governing Board.

Management Team

Strategic Management / Executive Committee

Strategic Management

Mrs. Rhoda Appiah was appointed as Head of Communication and Public Education Department in January 2021. She replaced Mr. James Lartey who moved to the Administration Department following the retirement of Mr. Jones Ofosu in 2020. Mrs. Cynthia Adwoa Dapaah, Head, Legal Department also resigned in the same year, her position was held by Mr. William Agbavitor, a senior legal officer.

Executive Committee

As part of the implementation of the new FDA Organogram, four (4) Deputy Chief Executive Officers and sixteen (16) Directors were appointed. In November 2021, the FDA Executive Committee was formed to replace the FDA Strategic Management as part of the implementation changes introduced by the new organizational structure. See appendix II for the list of members of the FDA Executive Committee

Middle Level Management

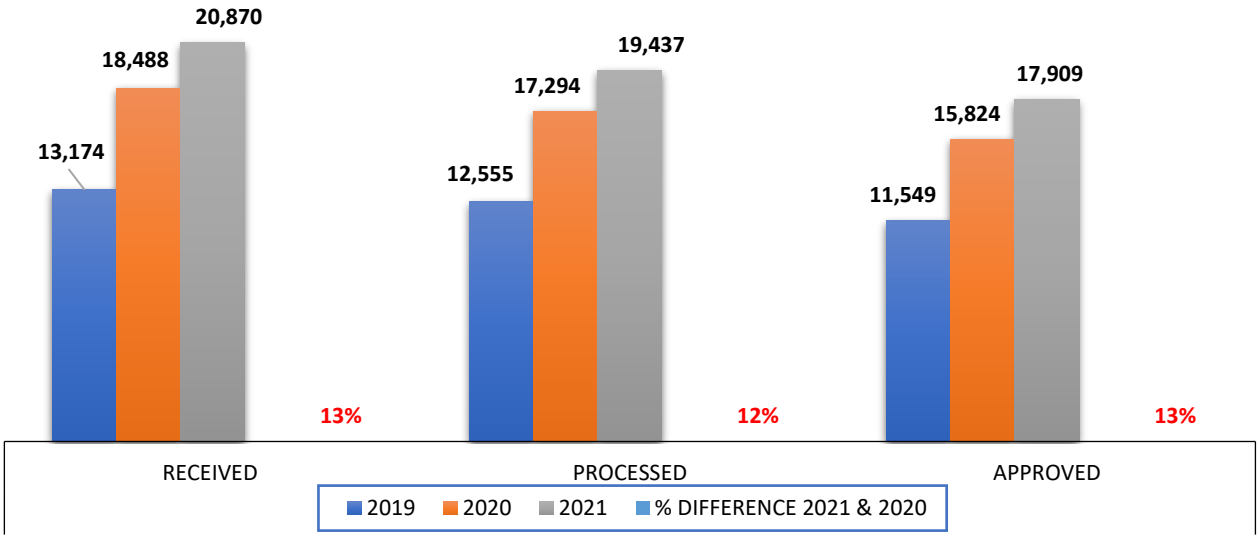
The membership of Middle Level Management was also reconstituted following the implementation of the new organogram. See appendix III for list of members of the FDA Middle Level Management.

3.0 2020 OPERATIONAL PERFORMANCE

3.1 Registration of FDA regulated products

The FDA has the following six (6) registration Departments: Food Evaluation and Registration, Drug Evaluation and Registration, Vaccines and Biological Products, Herbal Medicine, Medical Devices, and Cosmetics and Household Chemical Substances Departments. The graph below shows the performance of the product registration for all regulated products from 2019-21.

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

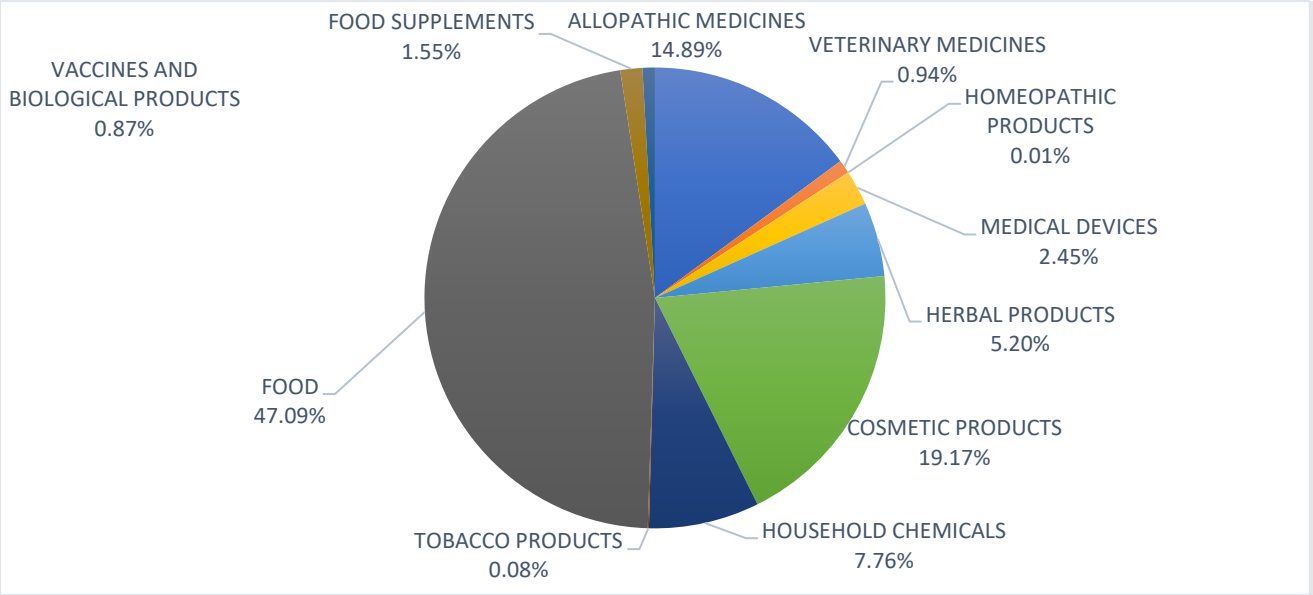


Source: *FDA Monitoring and Evaluation Department (2021)*

The 2021 annual target for the registration of FDA regulated products was eighteen thousand, three hundred and eighty-one (18,381). By the end of the year, a total of twenty thousand, eight hundred and seventy (20,870) products were received for registration, achieving 114% of its annual target. Out of the number of products received for registration, nineteen thousand, four hundred and thirty-seven product applications were processed, achieving 93% of its target of twenty thousand, eight hundred and seventy (20,870).

There was a 13% increase in products received in comparison to the previous year. Seventeen thousand, nine hundred and nine (17,909) products were approved as compared to fifteen thousand, eight hundred and twenty-four (15,824) products in 2020; representing an increase of 13% over the previous year's performance; out of this, number 65% were foreign products and 35% local products.

Figure 3.1-2: Categories of Products Registered

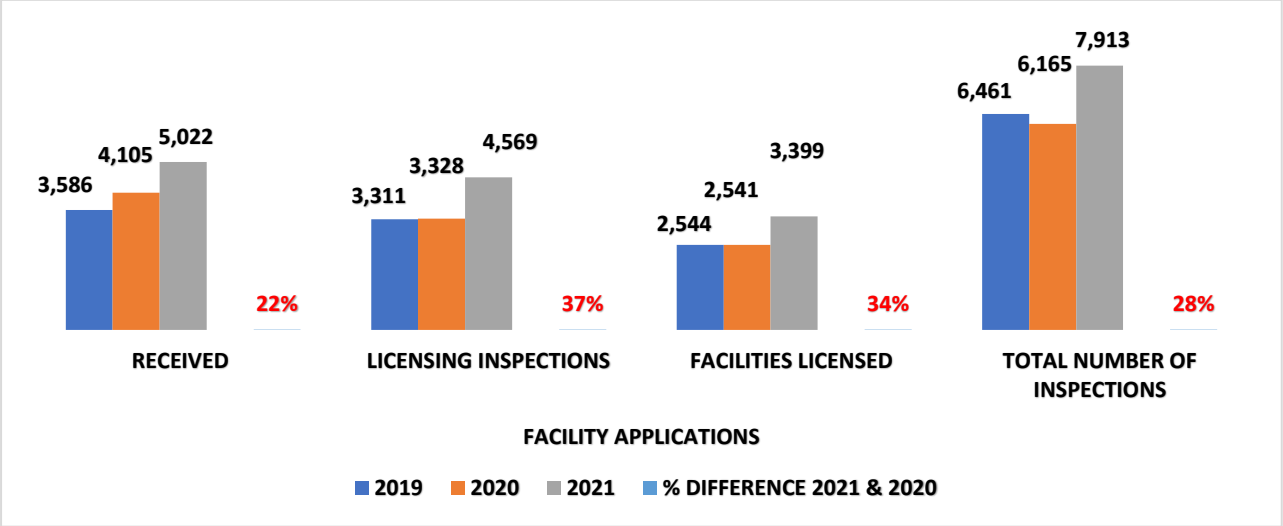


***Source**: FDA Monitoring and Evaluation Department (2021)*

3.2 Licensing of facilities regulated by the FDA.

The FDA has the following departments involved in the licensing of facilities: The Drug Inspectorate, Food Enforcement, Medical Devices, Cosmetics, Household Chemical Substances, Food Safety Management, Animal Products, and Agro-Produce and Biosafety Departments. The FDA operates a centralized system of licensure for facilities nationwide at the Head Office in Accra.

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



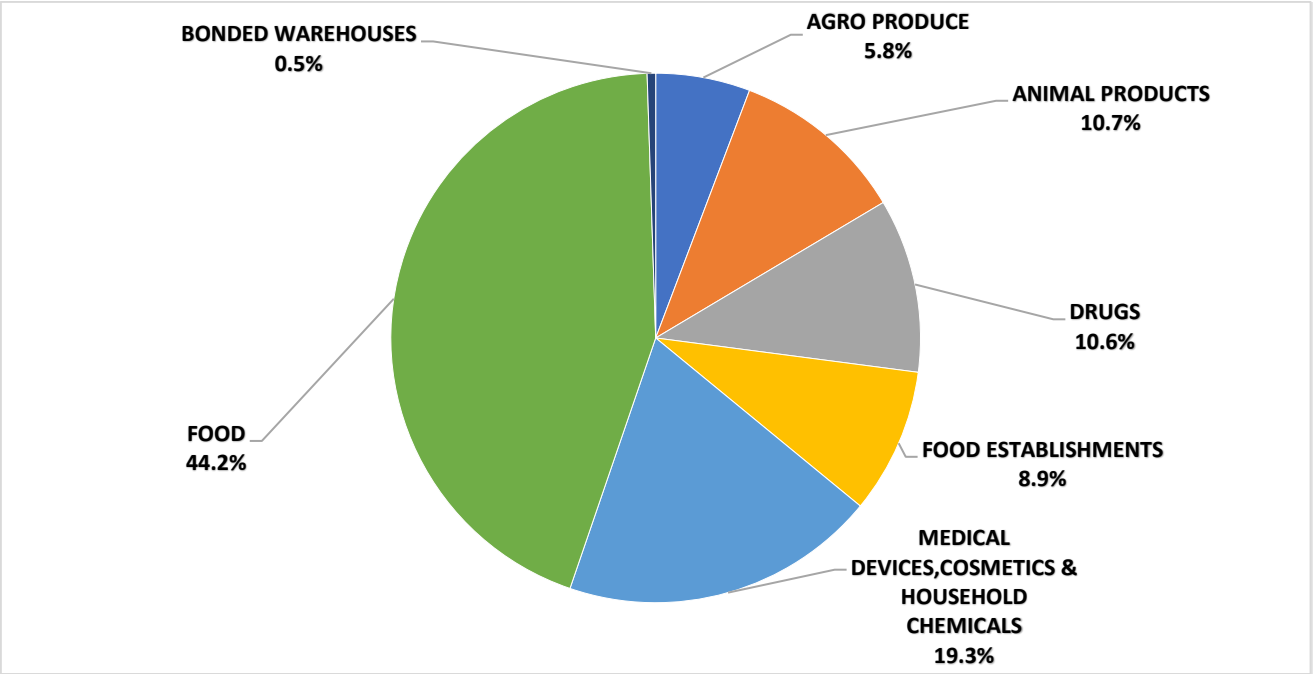
Source: *FDA Monitoring and Evaluation Department (2021)*

The 2021 annual target for licensing of facilities was six thousand and seven (6,007). By the end of the year, a total of five thousand and twenty-two (5,022) applications for facility license were received, achieving 84% of its annual target. The institution conducted four thousand, five hundred and sixty-nine (4,569) licensing inspections for the number of facility licensing applications received, achieving 91% of its target for the period under review. This represents a 37% increase over the number of licensing inspections conducted in 2020. In total, three thousand three hundred and ninety-nine (3,399) facilities were licensed in 2021, representing a 34% increase compared to the performance in 2020. A total of seven thousand, nine hundred and thirteen (7,913) inspections were conducted in 2021 as shown in the graph above, representing a 28% increase over the previous year's performance.

The FDA progressive license scheme (PLS) continues to support micro, small and medium scale enterprises (MSMEs) achieve regulatory compliance for quick market access. Since it was launched in June 2020, licensed facilities increased from one hundred and five (105) to seven hundred and twenty-eight (728) facilities; and food and cosmetic products registered increased from four hundred and four (404) to one thousand, seven hundred and forty-seven (1747) products under this flagship initiative.

The figure below shows the categories of facilities licensed:

Figure 3.2-2: Categories of Facilities Licensed

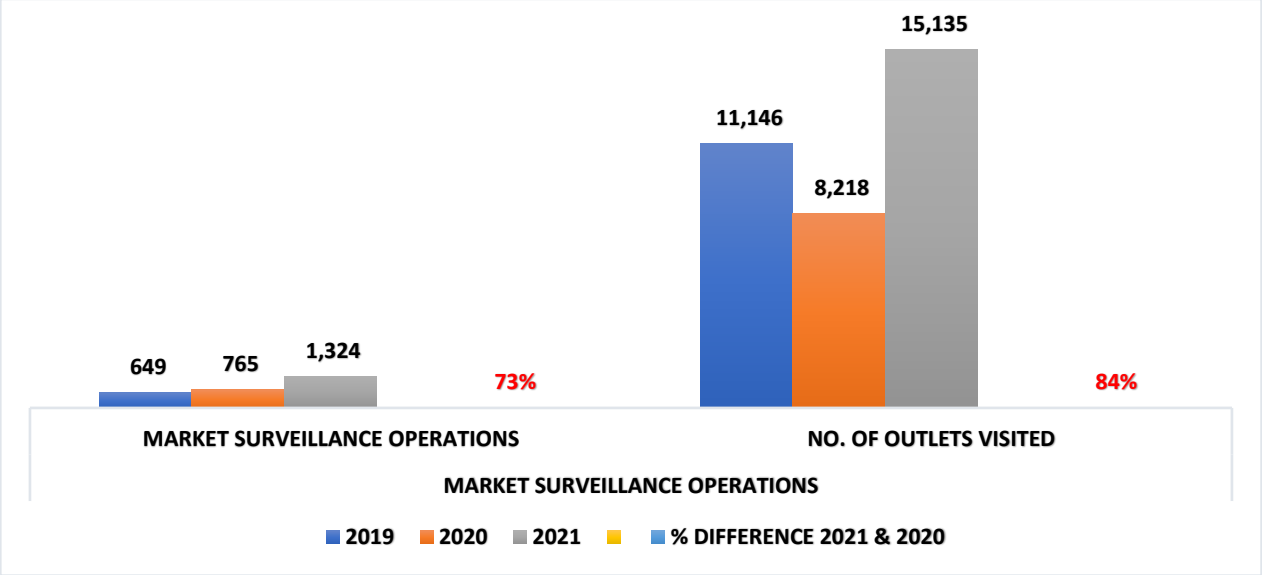


***Source**: FDA Monitoring and Evaluation Department (2021)*

Food facilities represent the highest proportion of licensed facilities within the FDA (44.2%), Medical Devices, Cosmetics and Household Chemical Substance facilities are the second highest (19.3%) with bonded warehouses being the least (0.5%). The FDA continues to work assiduously in bringing facilities across all categories into compliance.

3.3 Market surveillance operations

Figure 3.3-1: Performance for market surveillance operations

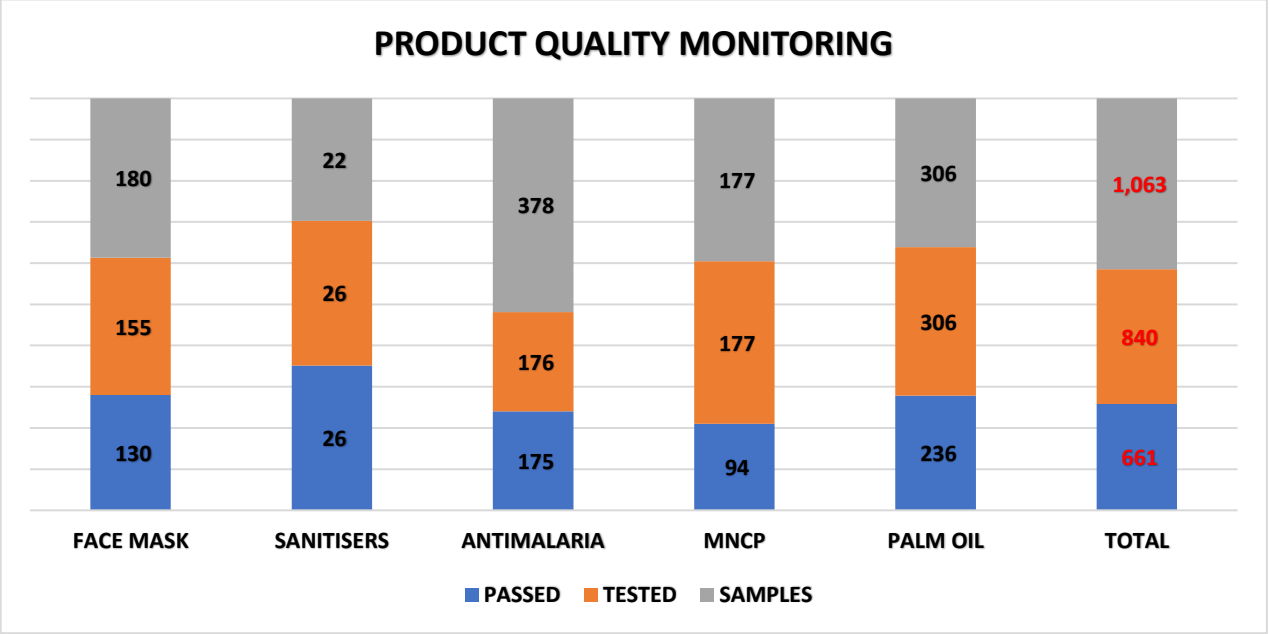


***Source**: FDA Monitoring and Evaluation Department (2021)*

The 2021 annual target for market surveillance outings and outlets visited were one thousand and twenty-two (1,022) and ten thousand four hundred and twenty-seven (10,427) respectively. As at the end of the year, one thousand three hundred and twenty-four (1,324) market surveillance outings had been carried out across the country, achieving 130% of its target, representing an increase of 73% over the previous year's performance. Fifteen thousand, one hundred and thirty-five (15,135) outlets were visited in 2021, a 145% achievement of its target for the year which was an 84% increase over the number of retail outlets visited in 2021. Twenty-two thousand, one hundred thirty-five (22,135) non-compliant products were identified during market surveillance outings, a 37% increase over the previous year.

As part of market surveillance operations at the FDA, the scope of Take Back Unwanted Medicines (TBUM) project was expanded to include Ashanti and Western Regions, resulting in an increase in the number of participating pharmacies from thirty-two (32) to one hundred and thirty-six (126).

Figure 3.3-2*: Product Quality Monitoring Achievement*



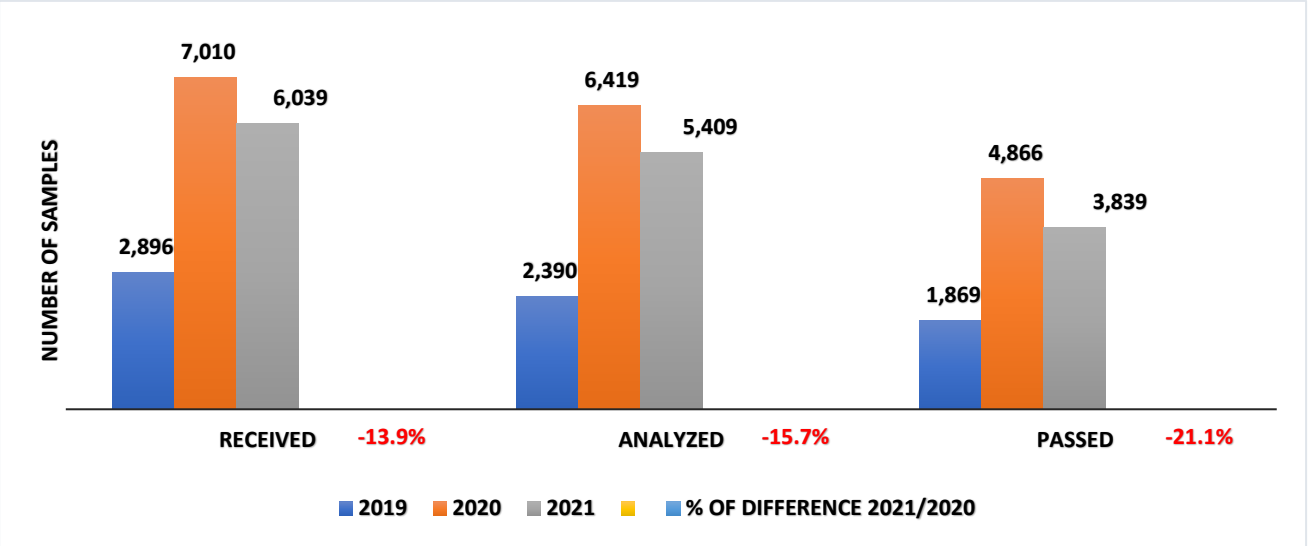
***Source**: FDA Monitoring and Evaluation Department (2021)*

In 2021, the Post Market Surveillance Technical Working Group was set up to strengthen product quality monitoring of pharmaceutical products. The goal this year was to conduct a risk-based post market quality survey of antimalarial drugs and maternal neo-natal and childbirth products, check the thickness, size and porosity of face masks as well as the alcohol content and pH of sanitizers. Palm oils were also to be tested for adulteration with Sudan IV dye. By the end of the year, one thousand and sixty-three (1,063) samples were collected through market surveillance activities. Out of this, eight hundred and forty (840) were tested and six hundred and sixty-one (661) passed analysis. FDA continues to conduct investigations on failed samples and hold engagements with all manufacturers and retailers of failed samples in bringing them into compliance.

For the product quality monitoring of palm oil samples, eighteen (18) markets were visited, and samples collected. Samples were tested and vendors of failed samples were invited for further investigations. FDA continues to make arrangements with the various market leaders across all regions in training palm oil aggregators and retailers on the risk posed by consuming Sudan IV.

3.4 Product Quality Testing

Figure 3.4-1: Product Quality Testing Performance



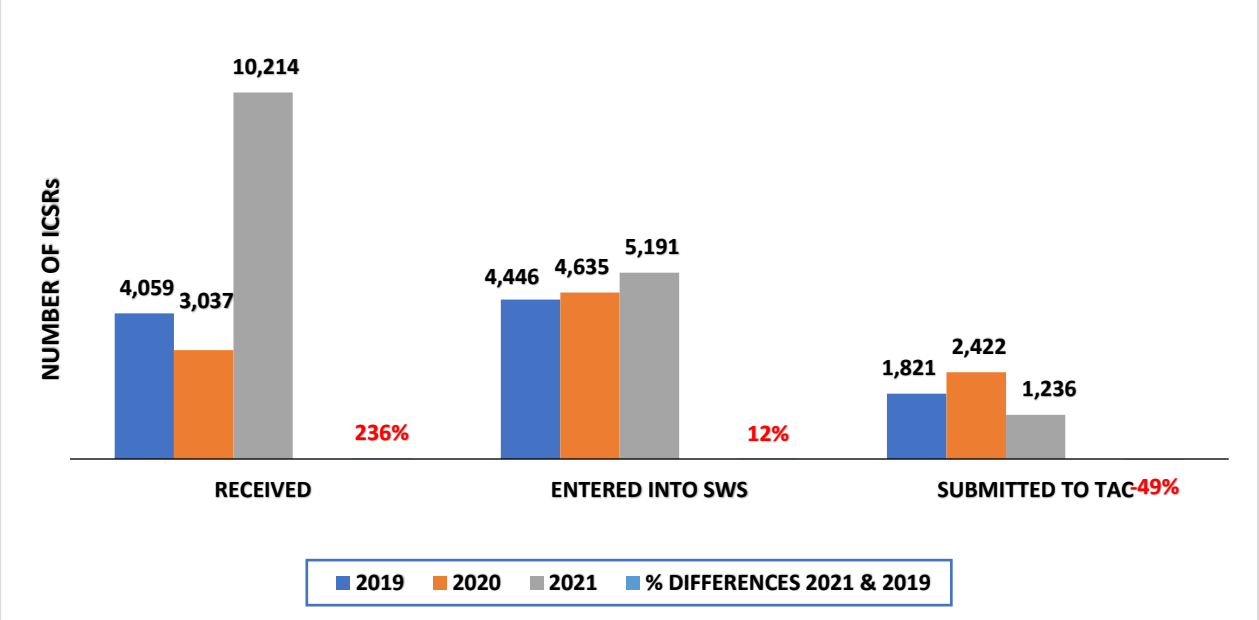
***Source**: FDA Monitoring and Evaluation Department (2021)*

The Centre for Laboratory Services and Research (CLSR) of the FDA targeted to analyze eighty-five (85) percent of all samples submitted to the laboratory. By the end of the year, CLSR had analyzed ninety (90) percent of samples submitted which represented an achievement of 106% of the target for the year.

A total of six thousand and thirty-nine products (6,039) were received by the CLSR for testing; revealing a decrease of 13.9% compared to the previous year. Out of the number, five thousand, four hundred and nine (5,409) products were analyzed; revealing a decrease of 15.7% over the previous year's performance. Three thousand eight hundred and thirty-nine (3,839) products passed whilst one thousand four hundred and eighty-four (1,484) products failed. The decrease in the number of requests and consequent analysis conducted is attributed to a decline in COVID-19 cases.

3.5 Safety Monitoring of Medical Products

Figure 3.5-1: Trend of safety monitoring performance



***Source**: FDA Monitoring and Evaluation Department (2021)*

The 2021 annual target for the number of Individual Case Study Reports (ICSRs) was two thousand six hundred and forty (2,640). By the end of the year, a total of ten thousand, two hundred and fourteen (10,214) Individual Case Study Reports (ICSRs) were received, achieving 387% of its annual target. Out of the number received, five thousand one hundred and ninety-one (5,191) ICSRs were entered into the safety watch system representing 201% of the annual target set in 2021.

The FDA received ten thousand, two hundred and fourteen (10,214) ICSRs; a 236% increase over the number received in 2020. In 2020 the reduced hospital attendance as a result of facilities offering only essential services was noted to affect the number of ICSRs received. Five thousand, one hundred and ninety-one (5,191) Individual Case Study Reports (ICSRs) were entered into the Safety Watch System (SWS); this was 12% more than was entered in 2020. The variation between the ICSRs submitted and those entered into the safety watch is as a result of a backlog of entries arising from manpower constraints from previous years, and the entry of forms that were previously exempted because they were classified as incomplete, but now have been cleared to be entered.

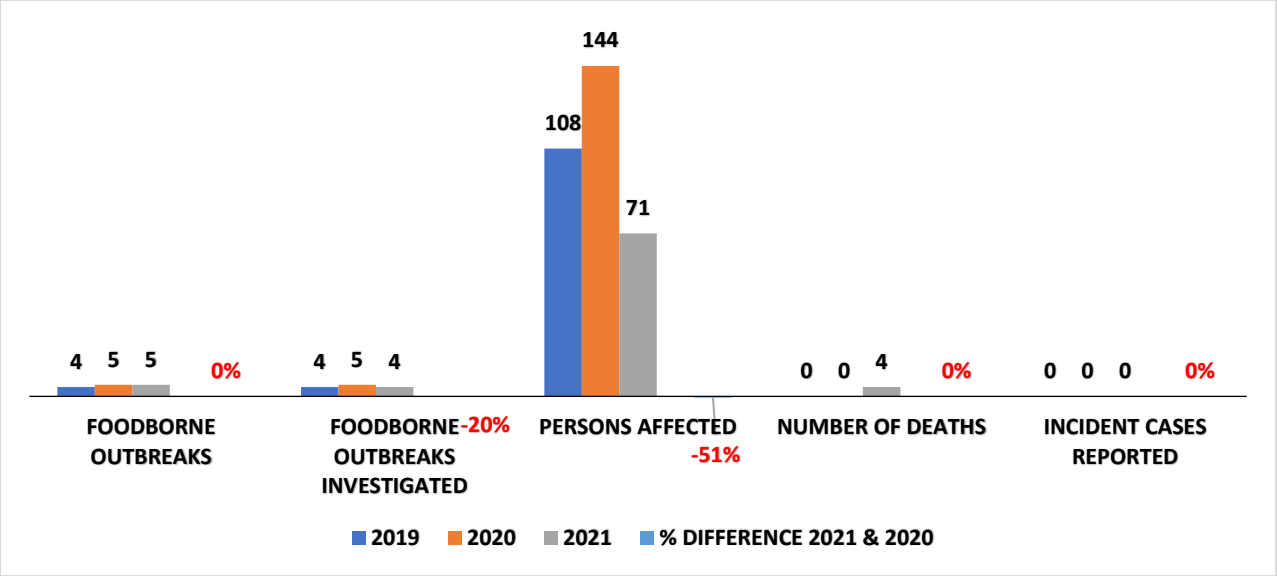
The Joint Covid-19 Vaccine Safety Review (JCVSRC) to assess adverse effects following COVID-19 vaccination was set up and a Safety Monitoring Call Centre for receiving adverse effects reports following COVID-19 vaccine deployment was also established this year.

The number of Individual Case Study Reports (ICSRs) submitted to the TAC reduced by 49% which was one thousand two hundred and thirty-six (1,236); there was a drop because causality assessment is only performed for serious AEFI reports which represented about 2% of ICSRs received.

3.6 Foodborne disease outbreaks and investigations indicators for 2019-2021

Food borne disease outbreak incidents remain unchanged at five (5) for 2021 compared to the previous year 2020. Seventy-one (71) persons were affected by these outbreaks.

Figure 3.6-1: Food borne disease outbreaks and investigations indicators for 2019-21



***Source**: FDA Monitoring and Evaluation Department (2021)*

There were four (4) deaths associated with the outbreaks investigated in 2021 out of which seventy-one (71) people were affected. No record of incident cases was collected for 2020 and 2021. Currently, no data is being collected on incident cases because there are no data sources. The Food Safety Emergency Response Plan (FoSERP) which will enable the FDA directly access and analyze data on incident cases of foodborne illnesses across the country through the Ghana Health Service Integrated Disease Surveillance and Response (IDSRS) was adopted and signed by the Minister of Health in April 2021.

3.7 Import Export Control

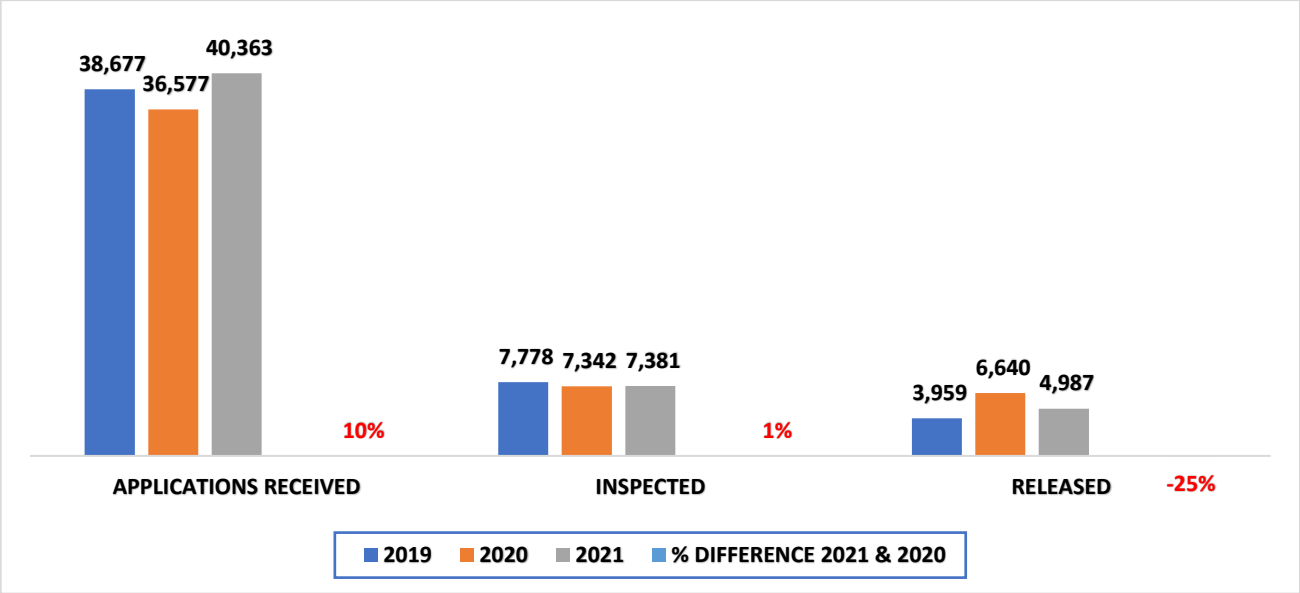
The 2021 annual target for the number of permit applications received was forty thousand, two hundred and fifty-seven (40,257). By the end of the year, a total of forty thousand, three hundred and sixty-three (40,363) permit applications were received, achieving 100% of its

annual target. Out of the number of permit applications received, thirty-nine thousand and ninety-nine (39.099) applications were processed, achieving 97% of its annual target of forty thousand, two hundred and fifty-seven (40,257). During the year, fifteen (15) bonded warehouses were inspected, leading to the licensing of eight (8) bonded warehouses.

A total of forty thousand, three hundred and sixty-three (40,363) permits were received and processed in 2021; this represents an increase of 10% from the previous year. Out of this number, thirty-five thousand, two hundred and twenty-four (35,224) permits were approved. Out of the total applications received for inspections, seven thousand, three hundred and eighty-one (7,381) consignments were duly inspected, representing a 1% increase in total applications received.

To curb the prevalence of unregistered products on the market through the Tema Port, the FDA launched the “zero tolerance” for the importation of unregistered products programme. The implementation of ‘no registration no importation’ at the Tema port in May 2021 led to a cumulative 71% decrease in number of detentions at the port.

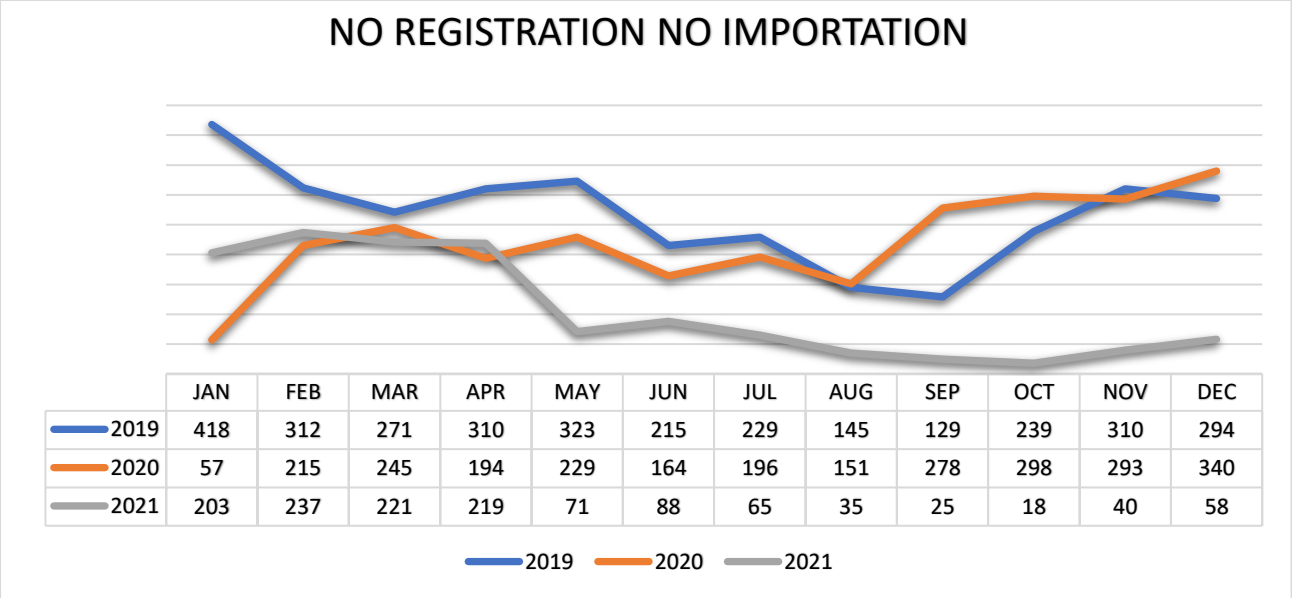
Figure 3.7-1: *Trend of import control performance*



***Source**: FDA Monitoring and Evaluation Department (2021)*

The number of applications received increased by 10% in the year 2021, the number of consignments inspected increased by 1% whilst the number of consignments released decreased by four thousand, nine hundred and eighty-seven (4,987) representing 25%; the number of consignments detained recorded two thousand, three hundred and ninety-four (2,394) representing 241% over the previous year. A total of two thousand, eight hundred and twenty-five (2,825) certificates of free sale were issued in 2021; an increase of 15% compared to 2020.

Figure 3.7-1*:* Trend of No Registration No Clearance Programme



	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
2019	418	312	271	310	323	215	229	145	129	239	310	294
2020	57	215	245	194	229	164	196	151	278	298	293	340
2021	203	237	221	219	71	88	65	35	25	18	40	58

***Source**: FDA Monitoring and Evaluation Department (2021)*

To curb the prevalence of unregistered products on the market through the Tema Port, the FDA launched the “No Registration, No Clearance” at the Tema port in May 2021 and that led to a cumulative seventy-one percent (71%) decrease in number of detentions at the Tema Port.

3.8 Clinical Trial Authorization

The 2021 annual target for the number of clinical trial authorization applications was eight (8). By the end of the year, a total of twenty-four (24) new clinical trial applications were received for consideration, achieving its annual target by 300%. Nineteen (19) amendments and one hundred and twenty-four (124) Ad-Docs were also received during the year.

The 2021 annual target for Serious Adverse Event reports was two hundred and forty (240). The Clinical Trials Department received Two hundred and forty-one (241) Serious Adverse Events (SAE) reports in 2021, achieving its annual target for the year. All SAE reports were submitted to the Technical Advisory Committee. Nine (9) GCP inspections were conducted

over the period under review with two hundred and fifty-one (251) participants trained; non-compliances observed were in the following proportions: critical non-compliances were 3%, major non-compliances were 58% were major, and forty (40) percent of non-compliances observed were minor. A total of forty-one (41) permits were issued for importation of investigational products out of sixty-three (63) applications.

All twenty-four (24) fresh Clinical Trial applications were received and reviewed, within the stipulated timelines (60 working days) however COVID-19 related trials were evaluated in less than 15 working days exceeding our target of 8 by about 200%. Out of sixty-three (63) applications received, forty-one (41) permits were issued for importation of investigational products.

The first clinical trial for herbal medicine, Nibima, for the treatment of COVID-19 was approved. FDA received the honorary excellence award (Government) at the Impact Africa summit held in Lagos in recognition of FDA's work in clinical trial regulation in Africa.

3.9 Support for Local Industry

3.9.1 Pharmaceutical Industry

The FDA in 2021 planned to review all block plan applications for 2021. As at the end of the year, the institution had achieved 100% of the target set for the year. Seventeen (17) applications were received for block plans in the year under review with a total of eighteen (18) applications reviewed and six (6) applications approved.

As a result of the Ghana GMP Roadmap, a total of 26 pharmaceutical companies out of 30 companies are either building new facilities or renovating pre-existing facilities to comply with GMP. As at the end of the roadmap, none of the facilities had been upgraded to Grade A, whiles there were 27 Grade B and 3 Grade C facilities.

Out of the twenty-five (25) CAPAs relating to the Ghana GMP Roadmap which were received and reviewed in 2020, the remaining fourteen (14) verification exercises from 2020 were carried out in 2021.

Technical assistance was offered to forty-eight (48) Ghana Enterprise Agencies (GEA) in Medical Devices Cosmetics and Household Chemicals manufacturing to support local micro-small-medium scale Industries through the National Board for Small Scale Industries.

3.9.2 Food Industry

3.9.2.1 Training Programmes

The 2021 annual target for the number of participants trained in Good Manufacturing Practices and Good Hygienic Practices was four hundred (400) for both trainings. By the end of the year, a total of four hundred and sixty (460) and two hundred and two (202) participants had been trained in Good Manufacturing Practices and Good Hygienic Practices respectively, these represents achievement of 115% and 51% of the annual targets set.

A total of Four Hundred and Sixty (460) participants from one hundred and seventy-four (174) food processing companies were trained in various aspects of Good Manufacturing Practices (GMP) compared to the previous year's figure of two hundred and eighty-one (281); this exceeded target of four hundred (400) participants target for 2021 due to the implementation of the Progressive Licensing Scheme (PLS).

Two hundred and two (202) staff from twenty- four (24) Food Service Establishments were trained in Food Safety and Good Hygienic Practices (GHP); compared to the previous year, which recorded three hundred and twenty- six (326) participants in 2020 representing a decrease of 38%. Training is done on demand based on in findings during inspections.

A fifty-one (51) percent achievement of its target of four hundred (400) participants from food service establishments and a thirty-eight (38) percent reduction in the number of participants (three hundred and twenty- six (326)) trained in 2020. The target for 2021 was not achieved as trainings are conducted on demand based on inspections of findings.

In 2021, one hundred and five (105) applicants completed the registration processes at the Ministry of Trade and Industry and are now in operation across the country as 1D1F facilities, 85% of these businesses received FDA's technical support.

3.9.2.2 Needs Assessments

FDA exceeded its target of forty (40) facilities by carrying out needs assessments for ninety (90) companies in 2021, however, this was a reduction in the number of needs assessments

carried out in 2020 (one hundred and two (102) which can be attributed to a reduction in the number of requests received from various food processing companies.

3.10 Tobacco and Substances of Abuse Control

3.10.1 Tobacco Control

The 2021 annual target for the number of tobacco product applications received was sixteen (16). By the end of the year, a total of seventeen (17) applications received, this represents achievement of 106% of the annual target for number of product applications received. The plan for 2021 was to process 100% of tobacco applications received. This target was achieved as all seventeen (17) applications received were processed by the end of the year.

Fourteen (14) out of the number of applications received were approved, a 13% increase in applications received as compared to the previous year. One Hundred and Twenty-One (121) permit applications were also received for tobacco products, out of this, one hundred and seventeen (117) tobacco permits were approved and four (4) were rejected. This translates to a thirty-one (31%) increase in permit issued over the previous year.
During the period under review, Ghana through the FDA ratified the Protocol to Eliminate Illicit Trade in Tobacco Product and FDA was also awarded the WHO Framework Convention on Tobacco Control (FCTC) Project 2030.

3.10.2 Controlled Substances Control

The Institution planned to issue thirty-nine (39) controlled substances of raw materials to importers and manufacturers. By the end of the year, the FDA achieved 69% of the Annual target set. Controlled substances were issued to twenty-seven (27) importers of raw materials and thirty-two (32) importers of finished pharmaceutical products (FPP). There was a 31% increase in allocation compared to the previous year.

Out of the two hundred and eleven (211) permit requests for controlled substances received, one hundred and sixty-eight (168) permits were issued, forty-three (43) rejected and seven (7) import permits were returned. There was fourteen percent (14%) increase in permit issued over the previous year. There was a 7% decrease in import permit applications rejected. Seven (7) import permits were returned since the suppliers of the controlled substances were not able to supply the products to the importers.

3.11 Public Awareness and Education

The annual target for the number of training programmes to be organised was sixty-four (64), by the end of the year one hundred and two (102) training programmes had been organized representing an achievement of 159% of the annual target.

One hundred and two (102) educational campaigns were organized for basic and secondary schools, tertiary institutions, marketplaces, transport terminals, non-governmental organizations, religious organizations and the media (radio, TV stations and electronic stations) which represented 137% increase in public engagement through public education on key and emerging safety issues compared to previous years.

3*.11* Communication and Public Education

The 2021 annual target for the number of press releases issued was twenty (20). By the end of the year, a total of twenty-nine (29) press releases had been issued; an achievement of 145% of the annual target.

Online activities in 2021 improved as compared to the previous years. There was an increase in the social media engagements, publications posted on the FDA social media handles, and online stories monitored over the period. The number of social media engagements as at the end of the year was twenty-one thousand three hundred and thirty-one (21,331) engagements.

The annual target for followers across Twitter, Instagram and Facebook in 2021 was thirty-eight thousand, five hundred (38,500). By the end of the year, the total number of followers across the aforementioned social media platforms was fifty-one thousand, nine hundred and ninety-five (51,995), achieving 135% percent of its annual target. The total number of new followers on FDA's official social media handles (LinkedIn, Twitter, Instagram & Facebook) increased from seven thousand six hundred and twelve (7,612) to twenty-four thousand one hundred and ninety-seven (24,197) representing an increment of 218%. Out of this number, LinkedIn, twitter, Instagram, and Facebook constituted 31%, 8%, 6% and 55% respectively of the number of new followers attained in 2021.

The FDA issued twenty-nine (29) press releases as compared to the nineteen (19) of press releases issue in 2020. In addition to this, the following were introduced during the year under review:

- the Food and Drugs Safety Line, audio-visual production tailored to address consumer concerns and misinformation on social media.

- two weekly e-publications “This week @ FDA” and “Last Week in Pictures” which cover FDA activities to create awareness among staff.

3.12 Projects

The following activities were undertaken by the institution for the various donor-funded projects during the year under review:

A steering committee meeting and project website were developed to enhance visibility of the donor for the ‘Building and Enhancing Regulatory Capacity in Africa’ (BERC-Africa), project sponsored by European & Developing Countries Clinical Trials Partnership (EDCTP)

As part of the AUDA NEPAD project to strengthen the safety monitoring system during Ghana's deployment of the COVID-19 vaccines, the FDA has led team meetings and monthly reporting on the project's progress to the donor to facilitate FDA’s activities towards delivering on the AU-3S project. The department has

The FDA coordinated a hands-on intensive 3-week training on clinical trial oversight and pharmacovigilance for ten (10) regulators from The Gambia, Liberia and Sierra Leone sponsored by Paul Erlich Institute (PEI). The training aimed at enhancing capacity in clinical trials and pharmacovigilance within the sub-region to improve the regulation of clinical trials and practice of effective pharmacovigilance in their respective countries.

A vaccine-related event response plan to strengthen post-vaccination safety surveillance was developed as part of the Task Force for Global Health project. Team meetings and monthly reporting on the project's progress were submitted to the donor.

The FDA organized and coordinated a one-day training for women-focused Civil Society Organization (CSOs) aimed to raise awareness of substandard and falsified medicines and health products. The project was sponsored by European Union (EU) Medi safe project, Expertise France

The first phase of the United Nations Children's Emergency Fund (UNICEF) Project on LI 1667 was coordinated in collaboration with Ghana Health Service to strengthen regulation and enforcement of the CODE on Breastmilk substitutes and subsequent World Health

Assembly resolutions. The team did a regional tour of 10 regions to ensure effective implementation of the International Code on Marketing of Breastmilk Substitutes.

4.0 2021 FINANCIAL PERFORMANCE

The FDA targeted to generate One Hundred Million, Five Hundred and Seventy-Three Thousand, Five Hundred and Ninety-Seven Ghana Cedis Ninety Pesewas (GHS 100,573,597.90) in the year 2021. By the end of the year, a total of one hundred and eight million, six hundred and sixty-seven thousand, one hundred and ninety-five Ghana Cedis and sixty-nine pesewas (GH¢ 108,667,195.69) was collected in 2021, an increase of 128% compared to revenue collected the previous year. Out of this number thirty-seven million, nine hundred and sixty-one thousand, nine hundred and eighty-nine Ghana Cedis and forty-one pesewas (GH¢ 37,961,989.41) was transferred to the consolidated fund whilst fifty-two million, seven hundred and fifty-eight thousand, five hundred and twenty-one Ghana Cedis eighty-six pesewas (GHS52,758,521.86) was spent on operations.

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

2021 ANNUAL BUDGET (GHS)			
	BUDGETED	**ACTUAL**	**VARIANCE**
Total Revenue	100,573,597.90	108,667,195.69	8,093,597.89
FDA Retention	50,286,798.95	76,067,036.98	25,780,238.08
Transfer to Consolidated Fund	50,286,798.95	37,961,989.41	(12,324,809.49)

Source*: FDA Financial Report (2021)*

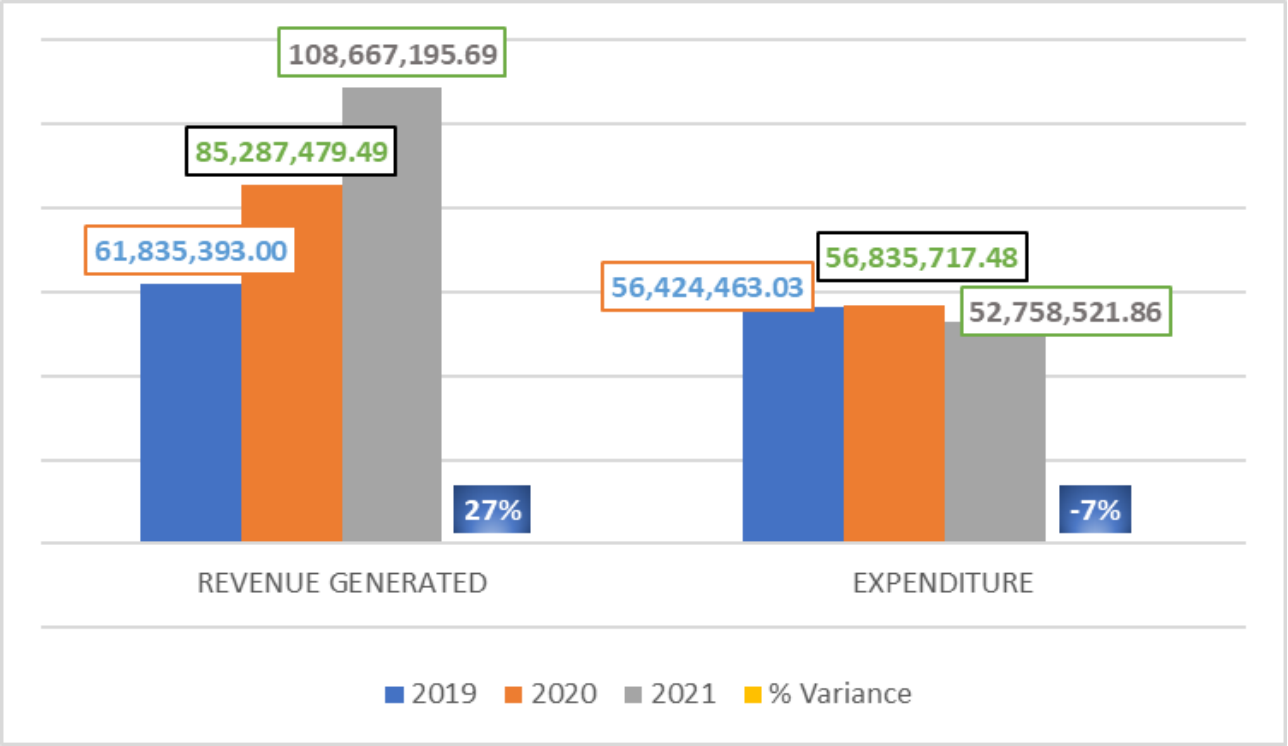
Table *4.0-2:* Expenditure Budget Performance

EXPENDITURE ITEMS	**BUDGET(GHS)**	**ACTUAL (GHS)**	**VARIANCE (GHS)**
IGF Compensation	16,250,540.53	25,938,269.01	9,687,728.48
Goods & services	25,875,230.17	23,103,499.18	(2,771,730.99)
Capital expenditure	8,161,028.28	3,716,753.67	(4,444,274.61)
Total	**50,286,798.98**	**52,758,521.86**	**2,471,722.88**

Source: *FDA Financial Report (2021)*

In 2021 the FDA exceeded its IGF compensation budget by 60% as indicated in table 3.11-2 above. The year also recorded a decrease in Goods and Services and capital expenditure by 11% and 54% respectively. The entire expenditure budget for 2021 exceeded its target by 2% due to the first payment of motivation, rent and additional allowances to staff to boost their morale.

Figure 4-*0-1: Revenue and Expenditure Performance*



***Source**: FDA Financial Report (2021)*

The Authority exceeded its revenue target by 8% in the year under review. The FDA was also privileged to have its revenue retention percentage increased from 50% to 70% in 2021 by the Ministry of Finance. The institution was able to reduce its expenditure by 7% and increased its revenue generation by 27% compared with 2020 figures.

4.1 Internal Audit

A total of five financial audits; twelve non-compliances were observed. The institution has recorded 100% lodgement for the past 3 years. In 2021, they executed all required financial (revenue and expenditure) audits; this included the Head Office, Tema, and KIA Offices, and the nine (9) Regional Offices, but could not achieve its target of visiting the regions twice in the year, due to manpower constraints. The directorate could not undertake performance audit as planned due to changes in planned requirement man hours for both financial and performance audit. The directorate couldn't attend any training in 2021 due to the COVID-19 restrictions but participated in conference organized by IAA at the Accra International Conference Centre. All requests received for review of payrolls, payment vouchers and verification of goods supplied to the FDA stores were completed.

On revenue audit infractions, the issue of non-timely lodging of money was not observed in the year 2021, same as in 2020. No major incident was recorded for the year under review.

On expenditure audits infractions, review of payment vouchers showed all payment vouchers were pre-audited, for 2021. There was no incidence of payment vouchers approved without requisite supporting documents. There was no incidence of un-retired funds. Compliance to financial regulations has improved tremendously. On payroll audit, there were no infractions observed for promotion updates, annual increments and presence of resigned staff on payroll. No other infractions were observed for the period under review. For the period under review, there was no infraction recorded for revenue, expenditure and payroll audits. This is a tremendous improvement for the organization and demonstrates the impact of effective internal audit on continuous improvement.

5.0 SUMMARY OF KEY ACHIEVEMENTS FOR 2021

5.1. ACCREDITATIONS

i. Re-certification to ISO 9001:2015 for administrative and operational procedures for FDA offices in Greater Accra, Volta, and Ashanti Regions.

ii. Scope of accredited tests under ISO 17025:2017 expanded from 40 to 48 tests for medicines, medical devices, microbiology and cosmetics and household chemical substances. This is the largest scope under a single roof in Africa.

iii. FDA's Laboratory has been audited and on course to be the first WHO Prequalified laboratory in West Africa.

iv. The FDA is now an associate member of International Collation of Medicines Regulatory Authorities (ICMRA). It is a voluntary, executive-level, strategic coordinating, advocacy, and leadership entity of regulatory authorities.

5.2 CAPACITY BUILDING

i. The FDA provided regulatory support to Nigeria in Good Distribution Practices. Rwanda, Senegal and Gambia have also extended similar invitations for regulatory support.

ii. MOU with the Ministry of Trade and Industry signed to increase our presence at the district level through its Business Resource Centers.

5.3 OPERATIONAL ACHIEVEMENTS

i. The first Food Safety Policy initiated in 2009 has been approved and will be launched in 2022.

ii. Commencement of toothbrush regulation as part of our efforts to protect public health and safety.

iii. Product evaluation and registration software has been deployed online to increase efficiency in product evaluation and registration. It has been rolled-out in all Regional Offices; and allows staff to work effectively from out of office locations.

iv. The FDA has inspected and released 20.2 million doses of COVID-19 vaccines.

v. Successful facilitation and completion of 2nd and 3rd phase of Enhanced Nutrition Value Added Chain (ENVAC) Project which supports agri-business to produce safe, quality and nutritious local staple foods.

vi. Develop a performance scorecard which ranks operational performance of departments and regional offices to support the annual staff awards programme.

vii. Developed and administered client and staff satisfaction surveys.

viii. Improvement in retrieval of administrative fines from defaulters; 60% of fines owed FDA retrieved so far.

ix. Product evaluation and registration software has been deployed online to increase efficiency in product evaluation and registration. This facilitated the roll-out in all Regional Offices; and also enabling staff to work from out of office locations.

x. The FDA with the GOG smart workplace has commenced automation of workflow for memos, leave management, procurement and finance. This has reduced FDA's carbon footprint in line with Government of Ghana's Climate Policy.

xi. Introduction of the GOIL GO-Card for fleet fuel management.

5.4 P*artnerships & International Collaborations*

i. FDA signed an MOU with the Ministry of Trade and Industry to increase our presence at the district level through their Business Resource Centres; providing essential services to FDA clients.

ii. FDA participated in the 2nd Intra-African Trade Fair, 2021, organised under the auspices of the Africa Continental Free Trade Area (AfCFTA) to facilitate Intra-Africa trade in line with the AfCFTA vision.

iii. FDA organized a Paul Ehrlich Institute sponsored training for 10 regulators from Gambia (5), Sierra Leone (3) and Liberia (2) in Clinical Trials Oversight and Pharmacovigilance.

iv. The FDA has been accepted as an associate member of International Collation of Medicines Regulatory Authorities (ICMRA). It is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities working together on emerging regulatory issues.

v. The FDA in collaboration with MUSIGA released an all-star anti-drug abuse campaign music video in the fight against substance abuse among the youth of Ghana.

5.5 AWARDS

i. The FDA received the Distinguished Service Award at the Ghana International Products Award.

ii. The FDA received an award for its Outstanding Contributions to the Healthcare Industry at the 3rd edition of the Ghana-West Africa Healthcare Excellence Awards.

iii. The FDA received the Honorary Excellence Award (Government) at the Impact Africa Summit in South Africa.

iv. The CEO of FDA, Mrs. Delese A. A. Darko was awarded the Quality Public Sector Leadership Award 2020 at the 5th Global Business Quality Awards 2021.

v. The Chief Executive Officer of FDA, Mrs. Delese A. A. Darko was awarded the Quality Public Sector Leadership Award 2020 at the 5th Global Business Quality Awards 2021.

6.0 MANAGEMENT OF CHALLENGES

6.1 COVID-19 impact on operations

- Desktop audits and consignment-based testing is used in place of foreign GMP inspections.
- Provision of personal protective equipment for inspectors.
- Staff working from home.
- Implementation of infection prevention control measures at FDA.
- Deployment of an online product registration system.

6.2 *Increase IGF Retention*

- Continuous dialogue with MOF for further assistance in IGF retention
- Continuous dialogue with Donor Partners for funding to support key activities

6.3 Inadequate logistics

- Risk based approach to planning and scheduling inspections.
- Staff use of personal computers.

7.0 PRIORITIES AND OUTLOOK FOR 2022

7.1 2022 – 2023 Health Sector Medium Term Development Plan (HSMTDP)

Align with the Health Objective 3 of the 2022-2025 HSMTDP (Heath Sector Medium Term Development Plan) through the following activities:

- Strengthen the enabling environment for improved breastfeeding and complementary feeding practices by institutionalizing BFHI in all health facilities in collaboration with relevant regulatory agencies and institutions, increase advocacy for improving social systems to support women and create breastfeeding spaces in public and workplaces, strengthen awareness and enforcement of regulation of marketing of breast- milk substitutes, increase staff competencies and skills and provide the requisite logistics and tools review and update (if needed) guidelines, policies, legal and other regulations related to breastfeeding and complementary feeding.

Technical Regulations

Operational Activities

The FDA will continue to strengthen the following key activities; product registration, facility registration, market surveillance, product quality monitoring, product quality testing, safety monitoring of regulated products, clinical trials and control of substances of abuse as well as the enforcement of the tobacco control regulations (LI 2247).

Enforcement of Sections 106 and 115 of Part 7 of Act 851

The FDA will secure accreditation from COTVET for its Qualified Supervisors Courses developed with the support from Skills Development Fund. This will enable FDA run same in Technical Universities and Private Consulting Firms across the country. This will ensure micro, small and medium scale enterprises (MSME) have easy access to accredited training institutions who will offer these for the food, cosmetics, household chemical substances and herbal medicine MSMEs.

Administration

Installation of lift at the Head Office.

Logistics

The FDA will procure additional vehicles and PCs to support its operational activities.

Human Resource Management

Implementation of new organogram

This process will continue with the confirmation of Ag. Directors, and appointment of Heads of Departments and Units.

Recruitment of Additional Staff

The FDA will recruit additional staff to strengthen its inspection and market surveillance activities across the country.

Management Information Systems

The FDA will continue development of systems to automate its operational workflow for product registration and facility licensing to enhance efficiency and facilitate out of office work. It will enable clients to make online submissions and follow up on progress of applications submitted. The FDA will continue with the automation of its administrative and operational work processes using the GOG Smart Workplace Platform.

Partnerships and International Collaborations

The FDA will fully operationalise FDA-GSA Operational Harmonisation Proposals with the establishment of systems to facilitate joint handling of client requests for registration, certification and export permits.

The FDA will continue to collaborate with the 1D1F secretariat to support manufacturing facilities to manufacture, distribute and sell FDA regulated products attain regulatory approval.

Strengthen collaboration with Ghana Enterprises Agency (GEA) to support micro, small and medium scale enterprises comply with codes Good Manufacturing practices using FDA's Progressive Licensing Scheme.

8.0 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 increase in applications submitted for products registration as well as facility licensing.

The expansion of scope for the FDA progressive licensing scheme to include herbal medicine and small-scale pharmaceutical medicines manufacturers is in progress; this will increase our performance in product registration, facility licensing and industrial support services.

The strengthening of capacity of Centre for Import and Export Centre's for import data mining will facilitate the recovery of lost revenue from companies avoiding FDA regulation at the Tema Port and consequently increased performance in revenue collection, product registration and facility licensing.

There will be deployment of 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, thus with the commencement of the 2021/22 national service period, the additional manpower of the national service persons will be used to bridge the gaps in the aforementioned operational areas.

9.0 APPENDICES

APPENDIX I – LIST OF GOVERNING BOARD MEMBERS

FDA GOVERNING BOARD MEMBERS				
S/N	**NAME**	**INSTITUTION**	**POSITION IN INSTITUTION**	**POSITION ON THE BOARD**
1	Dr. Sammy Ohene	University of Ghana Medical School	Head of Psychiatry Department	Chairman
2	Mrs. Delese A. A. Darko	Food and Drugs Authority	Chief Executive Officer	Member
3	Dr. Alhassan Emil Abdulai	University of Ghana. Accra.	Senior lecturer & Head of Departmental and Maxillo-Facial Surgery, School of Medicine & Dentistry	Member
4	Dr. Joyce Dontwi	Veterinary Services Directorate	Director	Member
5	Nana. K. Obiri	Ghana Federation of Traditional Medicine Practitioneers Association (GHAFTRAM)	National Organiser	Member
6	Prof. Charles Tortoe	CSIR- Food Research Institute	Acting Executive Director, CSIR- Food Research Institute	Member
7	Prof. Alexander Dodoo	Ghana Standard Authority	Executive Director	Member
8	Dr. Kofi Bobi Barimah	Centre for Plant Medicine Research	Ag. Executive Director	Member
9	Mrs. Anna Pearl Akiwuni-Siriboe	Ministry of Justice and Attorney General's Department	Chief State Attorney	Member
10	Mrs. Martha Osei	Communication for Development Centre	CEO, Communication for Development Centre	Member

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	Mrs. Delese A. A. Darko		Chief Executive Officer	Chairman
2	Mr. Seth K. Seaneke	Health Products & Technologies	DCE Health Products & Technologies	Member
3	Mrs. Akua O. Amartey	Technical Operations	DCE Technical Operations	Member
4	Mrs. Yvonne Nkrumah	Corporate Services	DCE Corporate Services	Member
5	Mr. Roderick Daddey Adjei	Food	DCE Food	Member
6	Mr. Eric Karikari-Boateng	Centre for Laboratory Services and Research	Directors, Centre for Laboratory Services and Research	Member
7	Mr. Emmanuel Yaw Kwarteng	Centre for Import & Export Control	Directors, Centre for Import & Export Control	Member
8	Mr. Nicholas Agbomadzi	Finance	Director, Finance	Member
9.	Mr. Edem Kofi Kugbey	Internal Audit	Director, Internal Audit	Member
10	Mr. Joseph Yaw-Bernie Bennie	Legal and Corporate Affairs	Director, Legal and Corporate Affairs	Member
11	Mr. Kwame Dei Asamoah-Okyere	Business Development & International Partnership	Director, Business Development & International Partnership	Secretary

APPENDIX III – LIST OF MIDDLE LEVEL MANAGEMENT

DIRECTORS				
S/N	**NAME**	**DIRECTORATE**	**POSITION**	**POSITION ON MIDDLE LEVEL MANAGEMENT**
	Mr. Joseph Bernie Bennie	Legal and Corporate Services	Head of Directorate	Chairman
1	Mrs. Faustina Atupra	Food Safety and Consumer Education	Head of Directorate	Member
2	Mr. Thomas Amedzro	Enforcement	Head of Directorate	Member
3	Ms. Maria Lovelace-Johnson	Inspectorate	Head of Directorate	Member
4	Mr. Ebenezer Kofi Essel	Industrial Support Services	Head of Directorate	Member
5	Ms. Nora Narkie Terlabie	Regional Operations	Head of Directorate	Member
6	Mr. Samuel Asante Boateng	Director, Drug and Herbal Medicine Registration	Head of Directorate	Member
7	Mr. Emmanuel Nkrumah	Director, Medical Devices, Cosmetics and Household Chemicals	Head of Directorate	Member
8	Dr. Edwin Nkansah	Clinical Trials and Safety Monitoring	Head of Directorate	Member
9	Mr. James Y. Lartey	Administration	Head of Directorate	Member
10	Dr. Mrs. Olivia Agyekumwaa Boateng	Tobacco and Substances of Abuse	Head of Directorate	Member
11	Mrs. Maureen Lartey	Food Registration and Applied Nutrition	Head of Directorate	Member
12	Kwame Dei Asamoah Okyere	Business Development and International Partnership	Head of Directorate	Member
14	Mrs. Naana Afrakoma Yawson	Supply Chain Department	Head of Department	Member
15	Mr. John Odai-Tettey	Central Regional Office	Ag. Regional Head	Member

16	Mr. Gorden Akurugu	Volta Regional Office	Regional Head	Member
17	Mr. Abu Sumaila	Western Regional Office	Regional Head	Member
18	Ms. Akua Amponsaa Owusu-Antwi	Bono Regional Office	Regional Head	Member
19	Mr. Samuel Kwakye	Eastern Regional Office	Regional Head	Member
20	Mr. Martin Kusi	Northern Regional Office	Regional Head	Member
21	Mr. Sebastian Hotor	Upper East Regional Office	Regional Head	Member
22	Mr. Albert Ankomah	Upper West Regional Office	Regional Head	Member
23	Mr. Samuel Siaw	Revenue and Expenditure	Head of Department	Member
24	Mr. Prince Oduro	Internal Audit	Head of Department	Member