
# FOOD AND DRUGS AUTHORITY

## 2019 ANNUAL REPORT

**JULY 2020**

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**EXECUTIVE SUMMARY**

The Food and Drugs Authority (FDA) is the national regulatory body in Ghana mandated by Parts 6, 7 and 8 of the Public Health Act, 2012 (Act 851) to assure the safety, quality and efficacy of human and veterinary medicines, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials, and the control and use of tobacco products, through the enforcement of relevant local and international standards to protect public health of the people in Ghana. This report gives account of the FDA's performance in the execution of its core mandate for the period January – December 2018.

*Product Registration*

A total of thirteen thousand, two hundred and eight (13,208) applications were received for the year under review; this represents an increase of 39% from the previous year, 2018. The number of processed applications increased by 51% representing twelve thousand, eight hundred and seventy-five (12,875)., Out of this number, a total of eleven thousand seven hundred and three (11,703) products were registered, representing an increase of 64% from 2018. Meanwhile, a total of one thousand, four hundred and seventy-two (1,472) applications were deferred, representing a decrease of 1% as compared to total products deferred in 2018.

*Facility Licensing*

A total of three thousand one hundred and sixty-four (3,164) applications were received for the year under review; this represents an increase of 36% from the previous year 2018. A total of five thousand, seven hundred and thirty-three (5,733) inspections were carried out in 2019; this represents 26% increase from the previous year. Three thousand one hundred and sixty- three (3,163) facilities were licensed, representing an increase of 47% from 2018.

*Market Surveillance*

A total of nine hundred and eighty-eight (988) market surveillance operations were carried out across the country; this marked an increase of 45% over the previous year's performance. The number of outlets that were visited increased by 31%. A total of one hundred and twenty-four thousand, nine hundred and five (124,905) non-compliant products were identified in trade; an increase of 269% over last year's performance.

As an organisation, the FDA undertook an average of nineteen (19) market surveillance operations each week for the year under review; an increase of 45% over the performance of the previous year, 2018. This translates to approximately four (4) market surveillance operations per working day across

the country.

*Product Testing*

The laboratory received two thousand eight hundred and ninety-six (2,896) products; this represents a decrease of 8% in products received in 2018. Out of this number, two thousand three hundred and eighty (2,380) products representing 82.2% were analysed; compared to the number of products analysed in 2018, it decreased by 15.4% in 2019. Approximately seventy-eight per cent (78%) of analysed products passed. In comparison to the 2018 data, the number of products that passed increased by 2.9% in 2019.

*Adverse Drug Reaction Monitoring*

The FDA received two thousand, seven hundred and eighty-seven (2,787) adverse drug reaction (ADR) reports, representing a decrease of 10% from 2018. The number of ADR reports submitted to the Technical Advisory Committee (TAC) decreased by 14%. A total of two thousand, four hundred and thirty (2,430) reports submitted to the TAC were reviewed, representing an increase of 82% from 2018.

*Food Borne Disease Surveillance & Investigation*

The number of outbreaks recorded decreased by 71.4%. There was no death associated with outbreaks recorded in 2019. Due to the absence of sentinel sites, there is no collection of data on incident cases. The breakthrough partnership with Ghana Health Service (GHS) which allows the FDA to incorporate its data needs into their Integrated Disease Surveillance and Response System will enable the FDA to collect data on incident cases of food borne illness across the country.

*Import and Export Control*

Out of thirty-eight thousand six hundred and seventy-seven (38,677) permit applications received, thirty-seven thousand, three hundred and eighty-seven (37,387) permits were issued in 2019. This represented a 7% increase in permits issued compared to 2018 data. Applications received for inspection increased by 31% with a total of thirty-five thousand, six hundred and ninety-eight (35,698) applications submitted; out of this figure, eighteen thousand and fifty- eight (18,058) consignments were duly inspected. This represented a 17% decrease in the number of inspections carried out in 2019 compared to 2018. For export control operations, the number of applications received for inspections, five hundred and ten (510), increased by 107% as compared to two hundred and forty-six (246) applications received in 2018.

*Clinical Trial Authorisation*

The Clinical Trials Department received a total of ten (10) new clinical trial applications, five (5) amendment and eighty-three (83) Ad-Doc applications for consideration; two (2) fresh and five (5) amendment applications were approved. Three hundred and fifty-one (351) Serious Adverse Events (SAE) reports were and submitted to the Technical Advisory Committee. Five (5) GCP inspections were conducted over the period under review; eighty-one (81) percent of non-compliances observed were minor, nineteen (19) percent were major and no critical non-compliance was observed. A total of seven (7) permits were issued for importation of investigational products out of fourteen (14) applications.

*Support for Local Industry*

Five (5) Pharmaceutical manufacturing companies; Ernest Chemist, Letap Pharmaceuticals, Amponsah Effah Pharmaceuticals, Eskay Therapeutics and Pharmanova Limited are set to complete construction of their new manufacturing facilities as part of the FDA-UNIDO sponsored GMP Compliance Road Map Project for large scale pharmaceutical companies by end of 2020.

The Food Industrial Support Service Department of The FDA received two hundred and sixty-one (261) training requests, representing a 20% increase in performance. The FDA organised thirty-six (36) training programmes, a decrease of 10% compared to 2018; however, the nine hundred and eighty-five (985) participants trained from three hundred and ten (310) companies represents an increase of 38% and 34% respectively. A total of one hundred and fifty-six (156) companies had their facilities licensed based on the support they received from the Food Industrial Support Service Department.

*Tobacco and Substance of Abuse Control*

Twenty (20) applications for registration of tobacco products were received, an increase of 33% compared to 2018; seventeen (17) applications were approved and three (3) rejected. A total of one hundred and eighty (180) permit applications for controlled substances were received, an increase of 34% compared to 2018; one hundred and thirty-five (135) applications were approved and forty-five (45) rejected. Sixteen (16) facilities that use controlled substances were audited; eighteen non-compliances were observed, a decrease of 44% compared to 2018. The FDA successfully organised the 2019 World No Tobacco Day celebrations across the country with support from the Regional Offices.

*Finance*

The FDA through its Fees, Charges and Administrative Fines collected a total of Sixty-One Million, Eight Hundred and Thirty-Five Thousand, Three Hundred and Ninety-Two Ghana Cedis and Eighty-Seven Pesewas (GHS 61,835,392.87). This represents an increase of 1.83% over the 2018 collections. The expenditure for 2019, fifty-four million, two hundred and forty-five thousand, seven hundred and ninety-three Ghana Cedis and eighty Pesewas (GHS 54,245,793.80), was an increase of 39.64% over that of 2018.

*Internal Audit*

For the period under review, there were no infractions recorded for revenue, expenditure and payroll audits. This is a tremendous improvement for the organisation and demonstrates the impact of internal audit on continuous improvement.

The performance of the FDA in respect of its regulatory functions of product registration, facility licensing, market surveillance, import and export control, product testing and safety monitoring increased. This follows the trend of the past two years – 2017 and 2018. There was, however, an 18% decrease in the total number of inspections. This notwithstanding, there are still gains to be made regarding process indicators such as the percentage of product applications processed, percentage of license inspections conducted, and percentage of submitted products tested. These gains appear to be locked up by resource constraints: human resource, vehicles, computers, application software and laboratory consumables and materials. Addressing these will enhance the Institution's performance in the respective areas. This will ensure that issues that limited performance in 2019 will be addressed to enhance performance in 2020.

## 1 INTRODUCTION

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

The FDA's critical role in the national health delivery system in Ghana cannot be overemphasized as the medical products it regulates are essential in the diagnosis, treatment and/or management of diseases. The importance of food in our lives is summed up by this Hippocrates quote: *"Let food be thy medicine and medicine be thy food."* The FDA ensures that the consumption of food does not contribute to the disease burden through sound food control practices. The effectiveness and efficiency of the FDA in the execution of its mandate is, therefore, critical to the health of the Nation.

**Functions of the FDA**

Parts six (6), seven (7) and eight (8) of Act 851 stipulates nineteen (19) functions for the FDA; these are in turn reflected by the respective Technical Divisions and Departments as well as Regional Offices within the organisation. The daily activities of all operational units of the FDA find their place within the following functions.

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, homeopathic, and herbal) and veterinary medicines, biological products, cosmetics, household chemical substances and tobacco products.
3. Register facilities for manufacture and storage, and vehicles for the transportation of products regulated by the FDA.
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. Issue 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 of Health on measures to protect public health.

This report gives account of the FDA's performance in the execution of its core mandate for the period January – December 2019.

## 2 MANAGEMENT AND STRUCTURE OF FDA

### FDA Governing Board

**Table 10.0-1:** The following members of the FDA Governing Board ended their tenure in 2019:

| NO. | NAME | POSITION | DATE OF APPOINTMENT | END OF TENURE |
|---|---|---|---|---|
| 1. | Rosalind Kainyah (Ms.) | Member | 3rd April, 2018 | December, 2019 |
| 2. | Augustine Ocloo (Prof.) | Member | 3rd April, 2018 | June, 2019 |
| 3. | Kenneth Gbeddy (Dr.) | Member | 3rd April, 2018 | May, 2019 |

Prof. Augustine Ocloo has been replaced by his successor, Dr. Joyce Dontwi, Director Veterinary Service Directorate, whilst Dr. Kenneth Gbeddy has been replaced by Dr. Kofi Bobi Barimah, Ag. Executive Director Centre for Plant Medicine Research. See appendix I for updated list of members of the Governing Board.

### Management Team

*Strategic Management*

Two management members retired from active service in 2019: Ag. Deputy Chief Executive responsible for Food Safety Division (FSD) and Food Inspectorate Division (FID), Mrs. Isabella Mansa Agra and Head of the Projects Research and Management Information Systems (PRMIS) retired after 14 years and 16 years respectively of service to the FDA. The Rector of the Ghana College of Pharmacists, a seconded staff of the FDA, Mr. Benjamin Kwame Botwe retired after 21 years of service. See appendix II for current list of Strategic Management members.

*Middle Level Management*

The FDA inaugurated a Middle Level Management in 2019 to play the role of translating and implementing the strategic decisions taken by Strategic Management; they have endeared themselves and worked towards improving the effectiveness and efficiency of FDA's operational activities. See appendix III for current list of Middle Level Management members.

# 3 TECHNICAL REGULATIONS

## 3.1 Product Registration

The FDA has six (6) registration departments as follows: Food Evaluation and Registration, Drug Evaluation and Registration, Biological Products, Herbal Medicine, Medical Devices, and Cosmetics and Household Chemical Substances Departments.

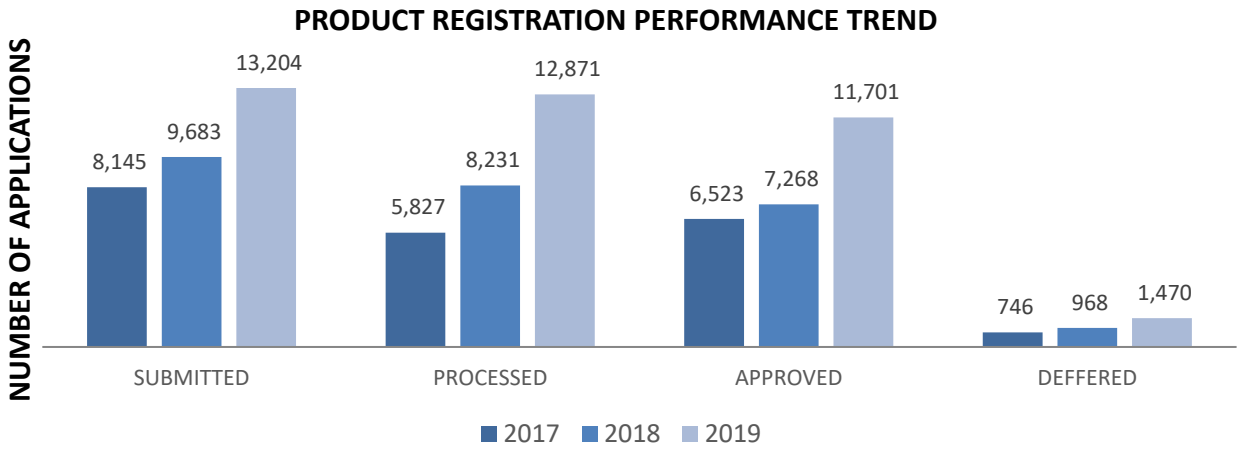


**Figure 3.1-1**: Trend for product registration performance indicators for 2017-19.

Figure 3.1-1 shows that a total of thirteen thousand, two hundred and four (13,204) applications were received for the year under review; this represents an increase of 36% from the previous year. Twelve thousand eight hundred and seventy-one (12,871) applications were processed, an increase of 56% compared to 2018; eleven thousand seven hundred and one (11,701) of products were approved, an increase of 61% compared to 2018; one thousand four hundred and seventy (1,470) products were deferred, an increase of 52% as compared with 2018.

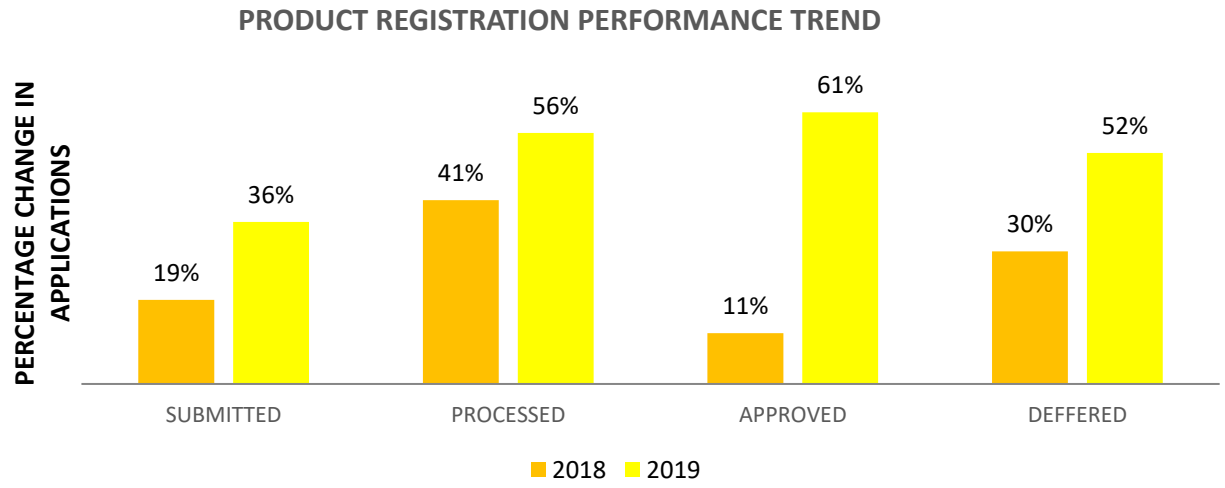


**Figure 3.1-2**: Trend of product registration application processing performance indicators showing percentage changes in performance relative to the previous year.

The year 2019 experienced a continued increase in performance across all the performance indicators of applications submitted, processed, and approved. Though the number of deferred applications increased, relative to the number of applications received for 2019, the percentage of processed applications that were deferred decreased by 1% as depicted in Figure 3.1-3.

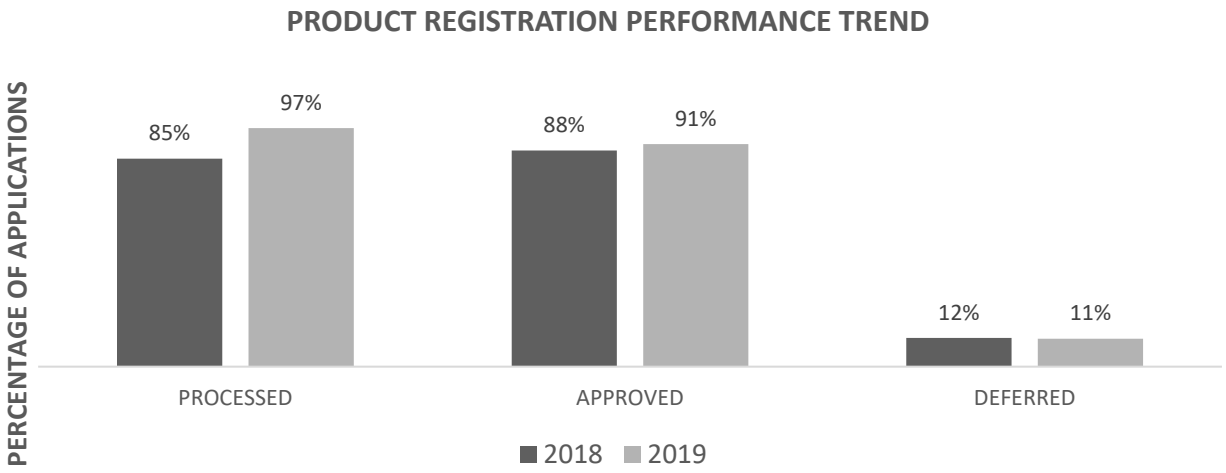


**Figure 3.1-3**: Trend of product registration application processing performance indicators showing proportions of applications received that were processed, approved and deferred for two consecutive years.

## 3.2 Facility Licensing

In 2019 the FDA had six (6) departments involved in the licensing of facilities; these are the Drug Inspectorate, Food Inspectorate, Medical Devices, Cosmetics, Household Chemical Substances Inspectorate, Food Safety Management, Animal Products, Agro Produce and Biosafety Departments and the Regional Offices.

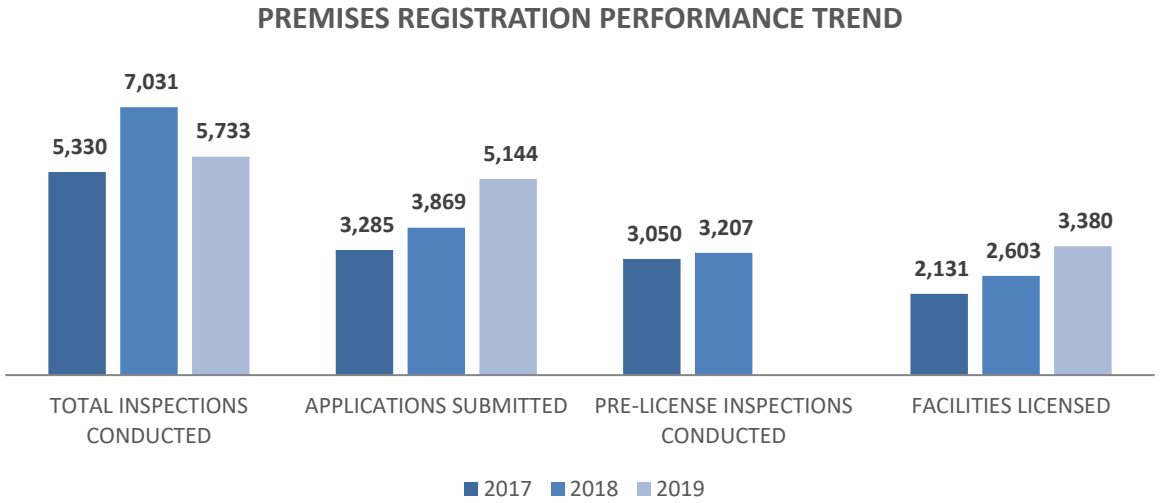


**Figure 3.2-1**: Trend for premises registration performance indicators for 2017-19.

A total of five thousand, seven hundred and thirty-three (5,733) inspections (pre-license, re-license, follow-ups and routine inspections) were conducted in 2019 as shown in Figure 3.2-1; this represents an 18% decrease from the previous year. Five thousand one hundred and forty-four (5,144) applications for registration of premises were submitted, an increase of 33% from 2018. Three thousand three hundred and eighty (3,380) facilities were licensed, representing an increase of 30% compared to 2018.

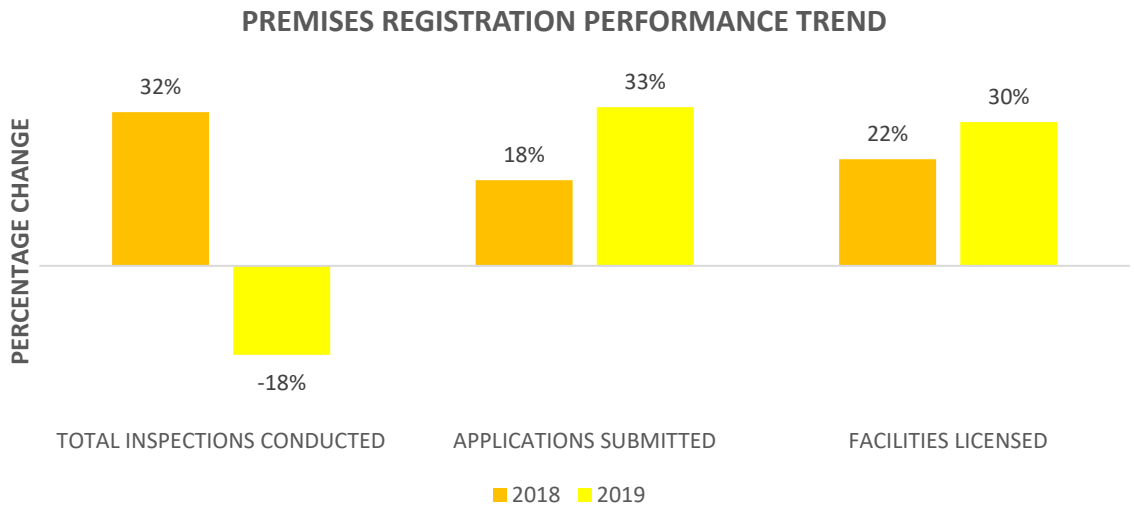


**Figure 3.2-2**: Trend of product registration application processing performance indicators showing percentage changes in performance relative to the previous year.

Except for total inspections that reduced, there was continued increased performance for applications submitted and facilities licensed.

### 3.3 Market Surveillance

In 2019, as part of the FDA's strengthening of market surveillance operations, two new market surveillance departments, Food Market Surveillance Department and Medical Devices, Cosmetic, Household Chemical Substance Market Surveillance Department were operationalised in addition to Drug Market Surveillance. Other Departments that perform market surveillance activities for specific category of products include the Animal Products Department, Agro Produce and Biosafety Department and the Regional Offices.

For 2019, a total of nine hundred and eighty-eight (988) market operations were carried out across the country; this marked an increase of 27% over the previous year's performance. The number of retail outlets visited increased by 19% totalling ten thousand, seven hundred and seventy-eight (10,778) retail outlets.

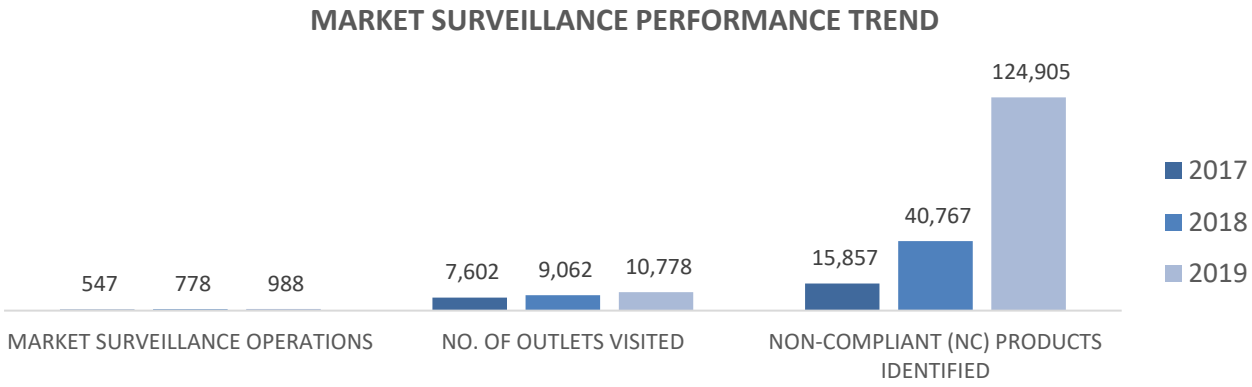


**Figure 3.3-1**: Trend of market surveillance performance indicators showing changes in performance for 2017-19.

A total of one hundred and twenty-four thousand nine hundred and five (124,905) non-compliant products were identified in trade; an increase of 206% as compared to the 2018 performance. Figure 3.3-1 shows sustained increase in performance for market surveillance operations carried out, retail outlets visited, identification of non-compliant products and detention of non-compliant products. The number of market surveillance operations increased consistently across the country as shown from Figure 3.3-2**.**

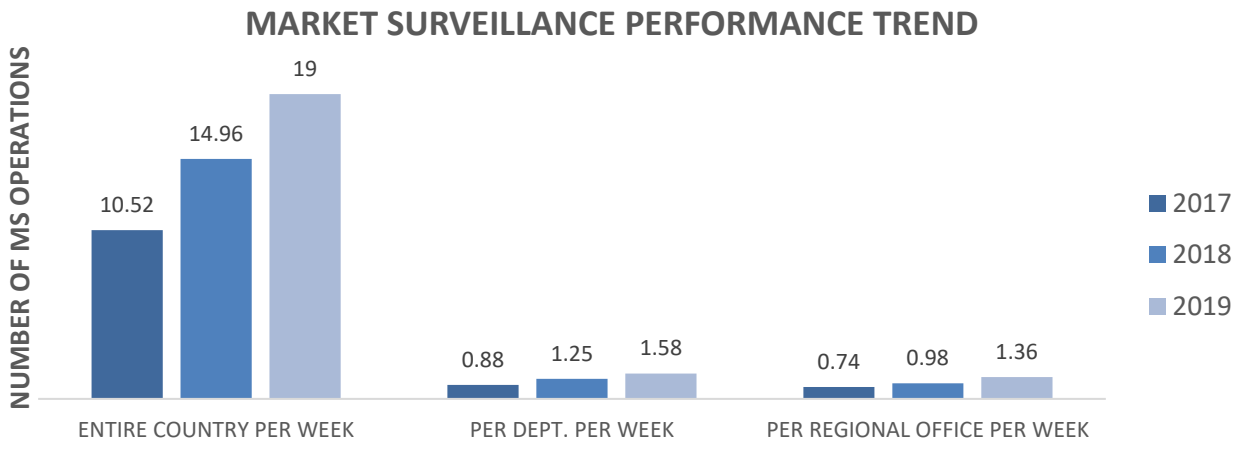


**Figure 3.3-2**: Trend of market surveillance performance indicators showing increased frequency of market surveillance operations across the FDA for 2017-19.

According to Figure 3.3-2, in 2019 the FDA undertook nineteen (19) market surveillance operations each week; this represents an increase of 27% over the performance of the previous year, 2018. These results confirm the increased market surveillance operations by the FDA; this means the FDA is present in the marketplace 32% and 27% each week in Greater Accra Region and the other Regions, respectively.

### 3.3.1 Product quality monitoring

*Food Products*

Out of seventy-eight (78) tomato paste/mix brands sampled and tested, 63 failed and 15 passed. Those that failed were found to contain starch and the colourant, Erythrosine, which are not permitted for use in such products. The FDA issued a recall of all affected brands from the market.

*Allopathic Medicines*

The FDA participated in a WHO Structured multi-country survey on quality of essential medicines in six African countries. Three hundred and twenty-five (325) samples of Antibiotics and Antimalarials were sampled from Northern, Volta and Greater-Accra Regions. One hundred (100) samples consisting of 20 antimalarials and 80 antibiotics were submitted to the FDA Laboratory Services Department for quality evaluation; out of the ninety-six (96) samples tested, eighty-five (85) passed quality evaluation (67 antibiotics and 18 antimalarials) and eleven (11) failed quality evaluation (2-ciprofloxacin brands and 9 amoxicillin+clavulanic acid formulations).

The following were sent to external laboratories; results are yet to be received:

- inphA GmbH Germany- Benzyl penicillin powder for injection (5 samples)
- Institute for Chemical Drug Control China National Institutes for Food and Drug Control (NIFDC)- All other antibiotics (40 samples). These have been returned due to administrative issues with Chinese Customs.
- BfArM Germany- Antimalarials, Artemether/ Lumefantrine ( 20samples)
- Shenzhen Institute for Drug Control (SIDC) China- Antimalarials- Dihydroartemisinin piperaquine and Artesunate Amodiaquine (10 samples)

The remaining 150 samples are with the DMSD. WHO is arranging funding for the analysis by an external laboratory.

*Cosmetics*

A total of one hundred and forty (140) cosmetics were sampled for quality evaluation; lotions (82), creams (46), shower gels (3), powder (5) and bar soaps (4). All the shower gels, powder and bar soap samples passed. For the lotions and creams, 45% and 41% respectively passed. The failed products were recalled and safely disposed-off.

### 3.4 Product Quality Testing

The laboratory received two thousand eight hundred and ninety-six (2,896) products; representing is a decrease of 8% due to the risk-based approach adopted by the Registration Departments. Out of this number, two thousand three hundred and eighty (2380) products representing 82% were analysed; the number of products analysed decreased by 14% compared to 2018. Seventy-eight (78) percent (1,856 products) of analysed products passed; however, the number of products that passed decreased by 11% as compared with total products that passed in 2018.

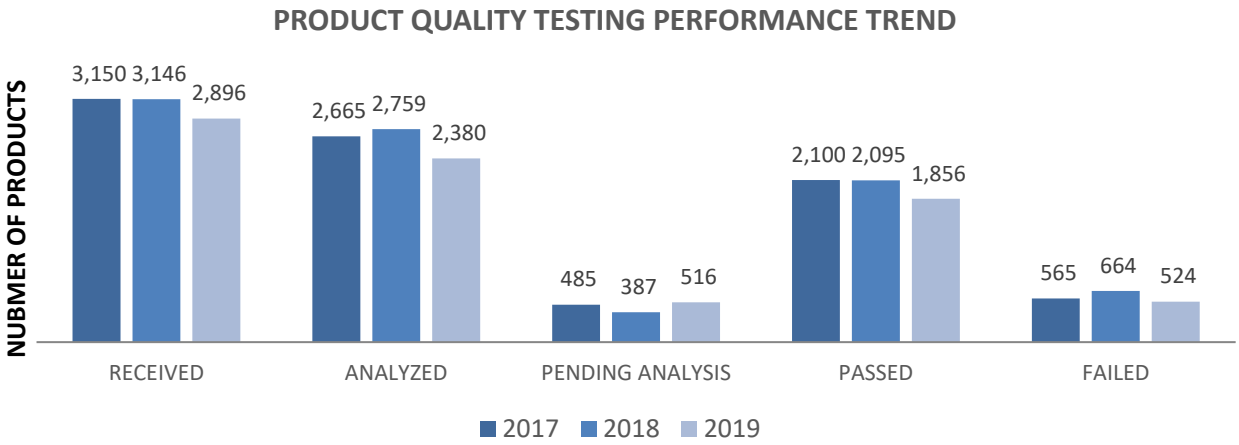


**Figure 3.4-1**: Trend of performance for product quality testing for 2017-19

Twenty-two percent (22%) of analysed products failed in 2019; this represents a 21% decrease compared to the 2018 product failure rate. Out of the total number of samples submitted for testing, 18% could not be tested; this is a 33% increase in the number of products pending analysis when compared to 2018.

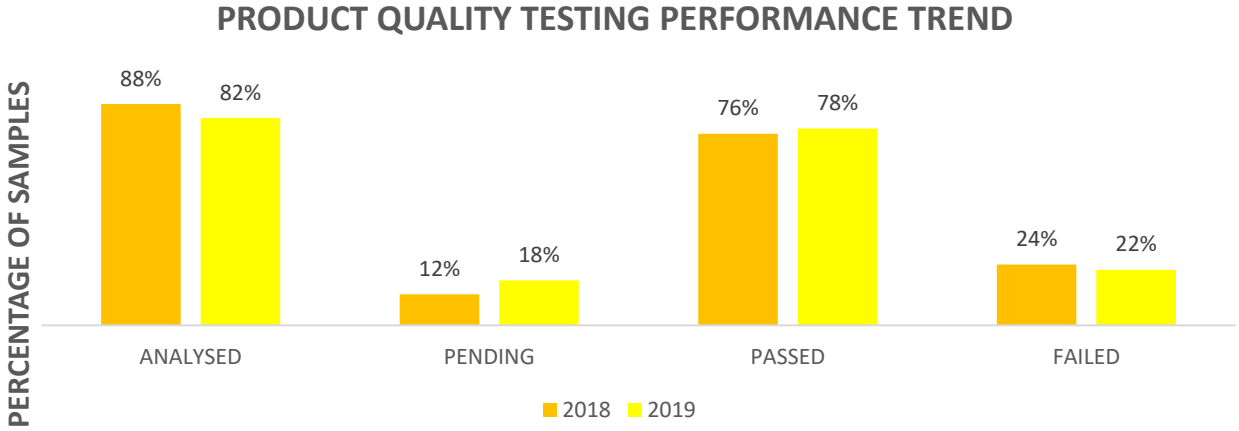


**Figure 3.4-2**: Comparing product testing performance in percentages for 2018-19

### 3.5 Adverse Reaction Monitoring

The FDA received three thousand, four hundred and forty-three (3,443) adverse reaction reports; this represents a decrease in reports submitted by 8% compared to 2018. Out of this, four thousand four hundred and forty-six (4,446) adverse reactions were entered into the Safety Watch System (SWS); this was 93% more than was achieved in 2018.

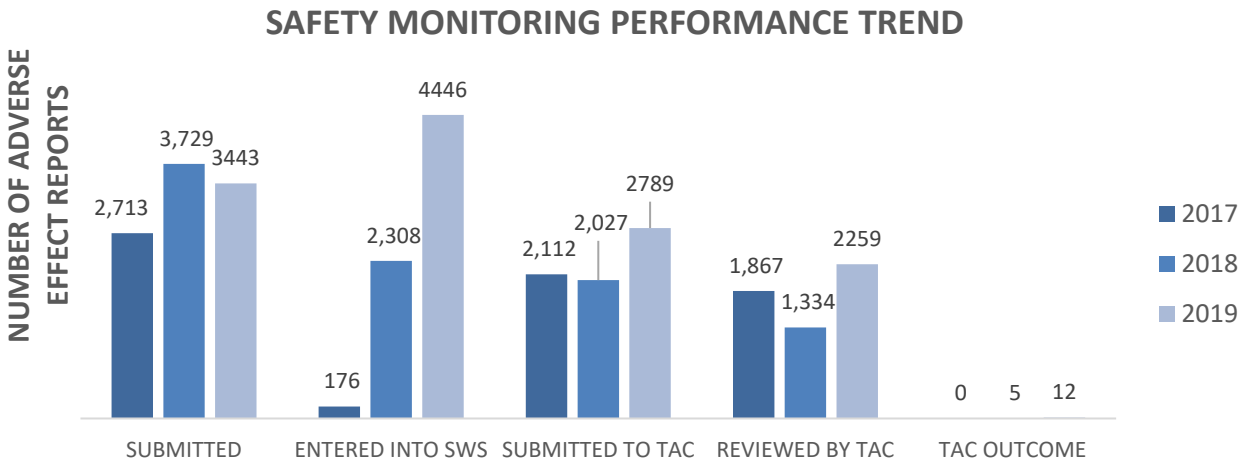


**Figure 3.5-1**:Trend of safety monitoring performance from 2017-19.

The number of adverse reaction reports submitted to the TAC increased by 38% to two thousand, seven hundred and eighty-nine (2,789) reports, and the number of adverse reaction reports reviewed by the TAC also increased by 69% compared to 2018

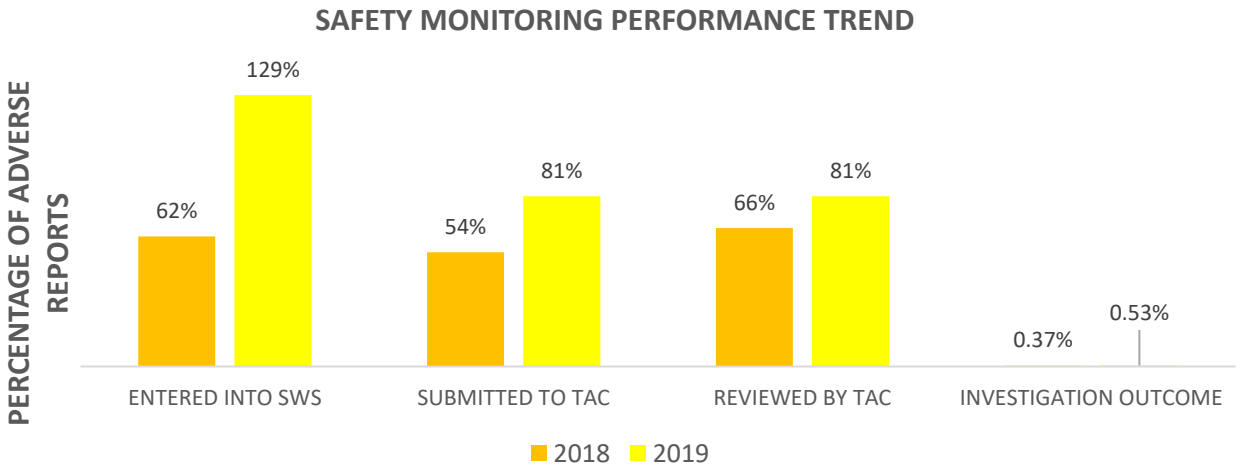


**Figure 4.6-2**: A 2019 to 2018 comparative performance of safety monitoring activities.

Comparing performance of 2019 to 2018, the percentage of adverse effect reports entered into the SWS increased by 129%, whilst the percentage submitted to and reviewed by the TAC increased by 81% and 81% respectively.

### 3.6 Food borne Disease Surveillance

The food-borne disease outbreaks increased by 113% to fourteen (14) outbreaks from six (6) in 2018; all these were investigated. The number of people affected by the outbreaks dropped by 36% to one hundred and sixty-one (161) from two hundred and fifty (250).

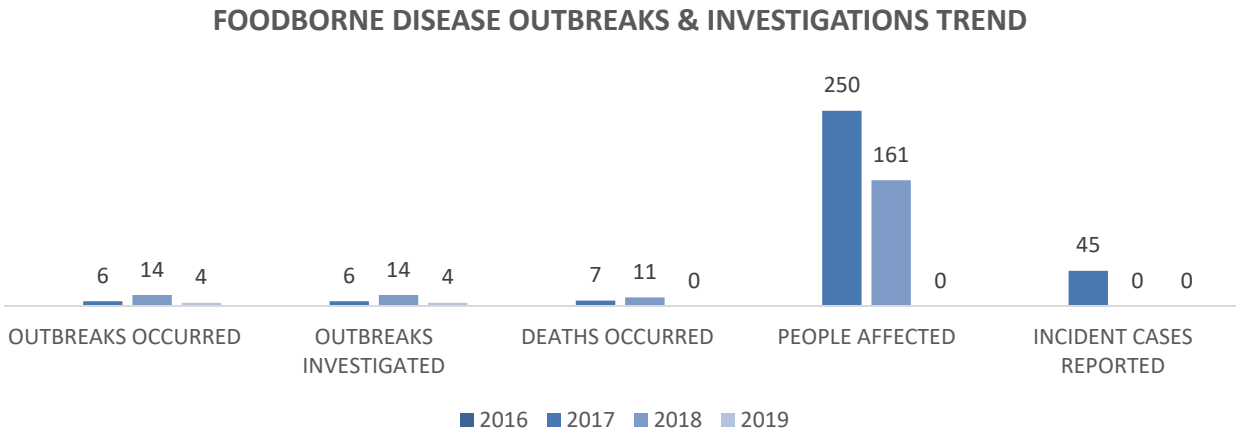


**Figure 3.6-1**: Trend of food borne disease outbreaks and investigations indicators for 2017-19

There was no death associated with the outbreaks investigated in 2019. No record of incident cases was collected for 2018 as well as 2019. Currently, no data is being collected on incident cases because there are no sentinel sites. The breakthrough partnership with Ghana Health Service (GHS) which allows the FDA to incorporate its data needs into their Integrated Disease Surveillance and Response System will enable the FDA to collect data on incident cases of food borne illnesses across the country. This will commence as soon as GHS staff receive the necessary training from the FDA.

### 3.7 Import and Export Control

A total of thirty-eight thousand, six hundred and seven-seven (38,677) permits were received and processed in 2019; this represents an increase of 6% from the previous year. Out of this number, thirty-seven thousand, three hundred and eighty-seven (37,387) permits were approved. Applications received for inspection of consignments increased by 31% to thirty-five thousand, six hundred and ninety-eight (35,698); out of the total applications received for inspections, eighteen thousand, and fifty-eight (18,058) consignments were duly inspected, representing 51% of total applications received (Figure 3.7-1 & Figure 3.7-2).

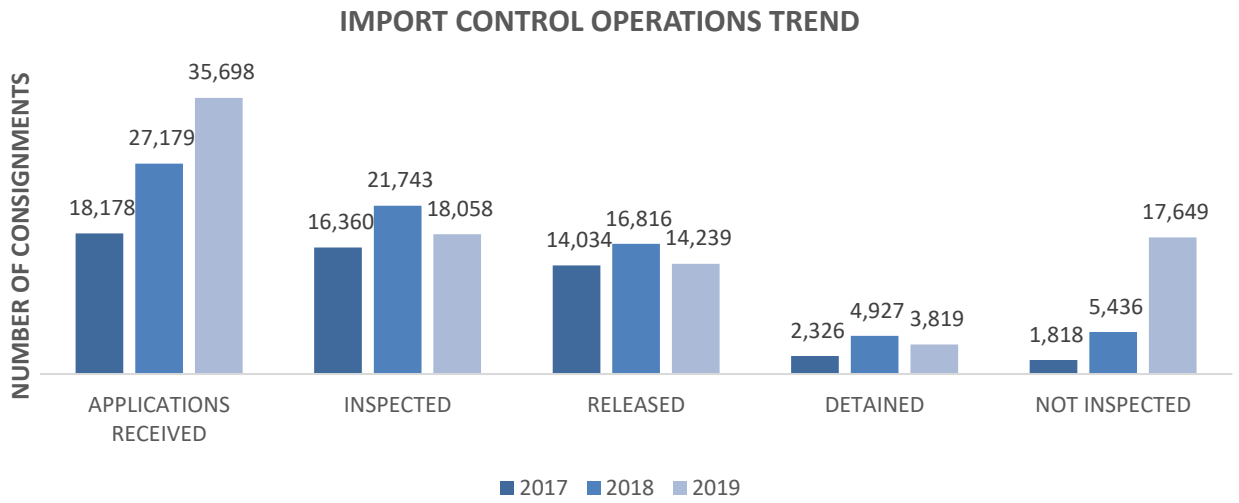


**Figure 3.7-1:** Trend of import control performance indicators for 2017-19

The number of consignments released decreased by 15%; the number of consignments detained also decreased by 22% in 2019, but in 2019 out of the total consignment inspected 21% were detained, with 49.4% of the total consignment received not inspected. The level of compliance by importers improved in 2018; thus, resulting in record low level of detentions at the port as compared with 2018 detention records. There is a need to put interventions in place to curb this problem; as it would make more time and resources available to deal with other pertinent issues by the market surveillance teams.

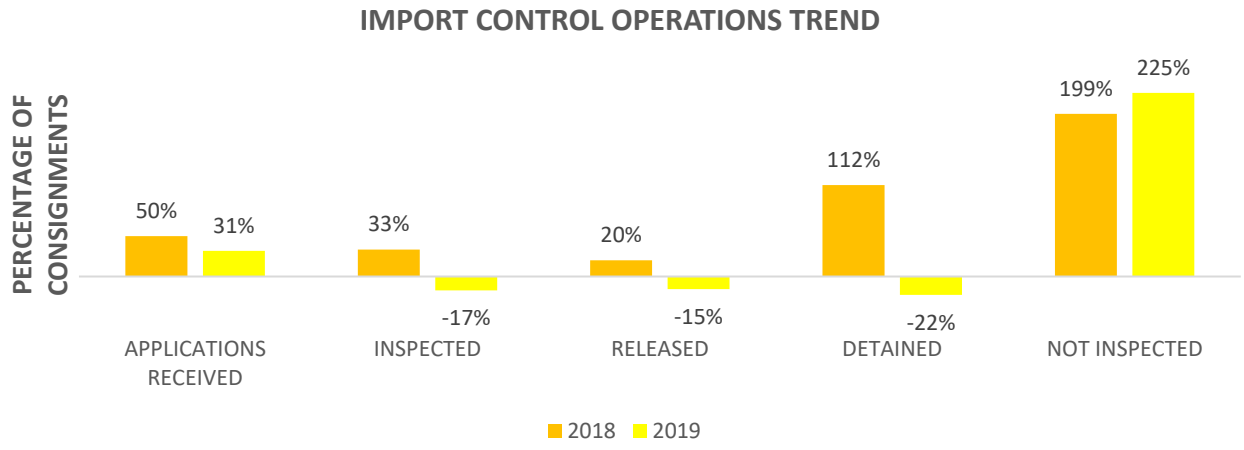


**Figure 3.7-2:** Trend of import control performance indicators showing percentage changes in performance relative to the previous year.

Comparing the performance of work output for 2019 with 2018, the number of consignments inspected increased by 51%, released increased by 79%, detained increased by 21% and those not

inspected increased by 49%. Though the percentage of detained consignments increased, the number of consignments detained reduced by 21% for 2019 relative to 2018. The increase in the number of consignments not inspected by 225% is attributable to the implementation of the National Integrated Risk Management System (NIRMS) at the Tema Port, where products in the green channel are not inspected.

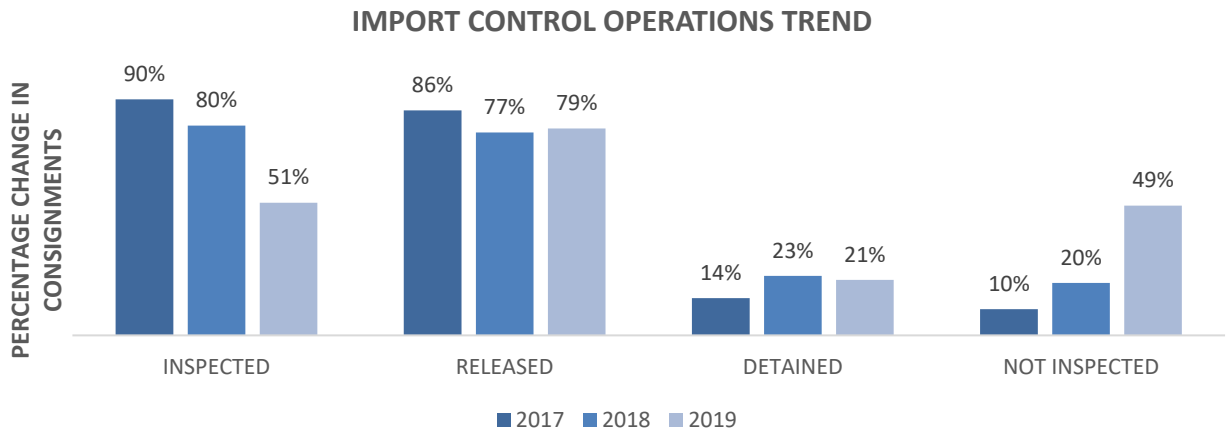


**Figure 3.7-3:** Trend of export control performance indicators for 2017-19.

According to Figure 3.8-3, five hundred and ten (510) applications for export were received, inspected and approved; an increase of 107% compared to 2018. A total of three thousand, three hundred and eighty-four (3,384) certificates of free sale was issued in 2019; a decrease of about 1% compared to 2018.

### 3.8 Clinical Trial Authorisation

The Clinical Trials Department received a total of ten (10) new clinical trial applications, five (5) amendment and eighty-three (83) Ad-Doc applications for consideration; two (2) fresh and five (5) amendment applications were approved. Three hundred and fifty-one (351) Serious Adverse Events (SAE) reports were received and submitted to the Technical Advisory Committee. Five (5) GCP inspections were conducted over the period under review; eighty-one (81) percent of non-compliances observed were minor, nineteen (19) percent were major and no critical non-compliance was observed. A total of seven (7) permits were issued for importation of investigational products out of fourteen (14) applications.

The following notable achievements were chalked by the Department:

- The Clinical Trial Department achieved WHO GBT maturity level 3.

- Organised a four-week course for thirteen (13) RCORE Fellows from eight (8) African countries.
- Organised its annual Good Clinical Practice training course which trained ninety-nine (99) participants.
- Trained Researchers at Navrongo Health Research Center, University of Health and Allied Sciences, School of Public Health Research Centre (Hohoe Campus), Malaria Research Center, Agogo.

Four (4) stakeholder meetings were organised for Clinical Trial researchers at the Greater Accra Regional (Ridge) Hospital, Accra, Komfo Anokye Teaching Hospital, Kumasi, Navrongo Health Research, Tamale and University of Health and Allied Sciences, Ho to introduce and solicit feedback on clinical trials regulatory framework, and existing clinical trials guidelines

## 3.9 Support for Local Industry

### 3.9.1 Pharmaceutical Industry

Five (5) Pharmaceutical manufacturing companies: Ernest Chemist, Letap Pharmaceuticals, Amponsah Effah Pharmaceuticals, Eskay Therapeutics and Pharmanova Limited are set to complete construction of their new manufacturing facilities as part of the FDA-UNIDO sponsored GMP Compliance Road Map Project for large scale pharmaceutical companies by end of 2020. Three (3) companies achieved Grade C rating bringing the total number of Grade C rated facilities to twenty-seven (27), a 13% increase compared to 2018. No new companies were admitted to Grade B in 2019, thus three (3) companies are currently rated Grade B. One (1) company achieved compliance to quality management system requirements bringing the total number of such companies to three (3) for 2019.

The FDA successfully commenced the regulation of small-scale pharmaceutical manufacturers (for extemporaneous preparations) in 2019. Two training sessions were organised for this industry training one hundred and seventy-four (174) participants from eighty-nine (89) companies.

### 3.9.2 Food Industry

*Training Programmes*

The Food Industrial Support Service Department of The FDA received two hundred and sixty-one (261) training requests, representing a 20% increase in performance. The FDA organised thirty-six (36) training programmes, a decrease of 10% compared to 2018; however, the nine hundred and

eighty-five (985) participants trained from three hundred and ten (310) companies represent an increase of 38% and 34% respectively. A total of one hundred and fifty-six (156) companies had their facilities licensed based on the support they received from the Food Industrial Support Service Department; this represents a 10% increase compared to 2018 performance.

A total number of forty-seven (47) participants were trained during the 2019 annual Food Safety Supervisors' Course (introductory level). Sixty-five (65) participants from the food industry were trained in Hazard Analysis Critical Control Point (HACCP) at the introductory level.

### 3.10 Tobacco and Substances of Abuse Control

*Tobacco Control*

Twenty (20) applications for registration of tobacco products were received, an increase of 33% compared to 2018; seventeen (17) applications were approved and three (3) rejected. One hundred and thirty (130) permit applications were received, an increase of 38% compared to 2018. Out of this number one hundred and twenty-seven (127) applications were approved and three (3) rejected.

*Controlled Substances Control*

A total of one hundred and eighty (180) permit applications for controlled substances were received, an increase of 34% compared to 2018; one hundred and thirty-five (135) applications were approved and forty-five (45) rejected. Sixteen (16) facilities that use controlled substances were audited; eighteen non-compliances were observed, a decrease of 44% compared to 2018.

*Public Awareness and Education*

The FDA successfully organised the 2019 World No Tobacco Day celebrations across the country with support from the Regional Offices. Over one thousand (1000) people were educated on the harmful effects of tobacco products with emphasis on tobacco and lung health. Nationwide media engagements on the print, electronic and social media platforms were organized to raise awareness on the health implication of tobacco use.

The Department organised one hundred and seventy-three (173) public education programmes on tobacco use and substance of abuse. The FDA collaborated with MUSIGA to compose a song on drug abuse.

### 3.11 Finance

The FDA through its Fees, Charges and Administrative Fines collected a total of sixty-one million,

eight hundred and thirty-five thousand, three hundred and ninety-two and eighty- seven Pesewas (GHS 61,835,392.87). This represents an approximate 2% increase in revenue collected compared to 2018 but fell short of our revenue target for 2019 by 4%. IGF retained in 2019 was Forty-Nine Million Eight Hundred and Thirty-Five Thousand Three Hundred and Ninety-Two Ghana Cedis and Eighty-Seven Pesewas (GHS49,835,392.87) - see Figure 3.11-1. The distribution of revenue collections for the Head Office, Import and Export Control Department (IECD) and Regional offices is shown in Figure 3.9-2. The contribution by the Head Office decreased by 1% to 61%, whilst that of IECD (Tema & KIA) increased by 5% to 33% and the Regional Offices increased by 13% to 6% of the total revenue collected.

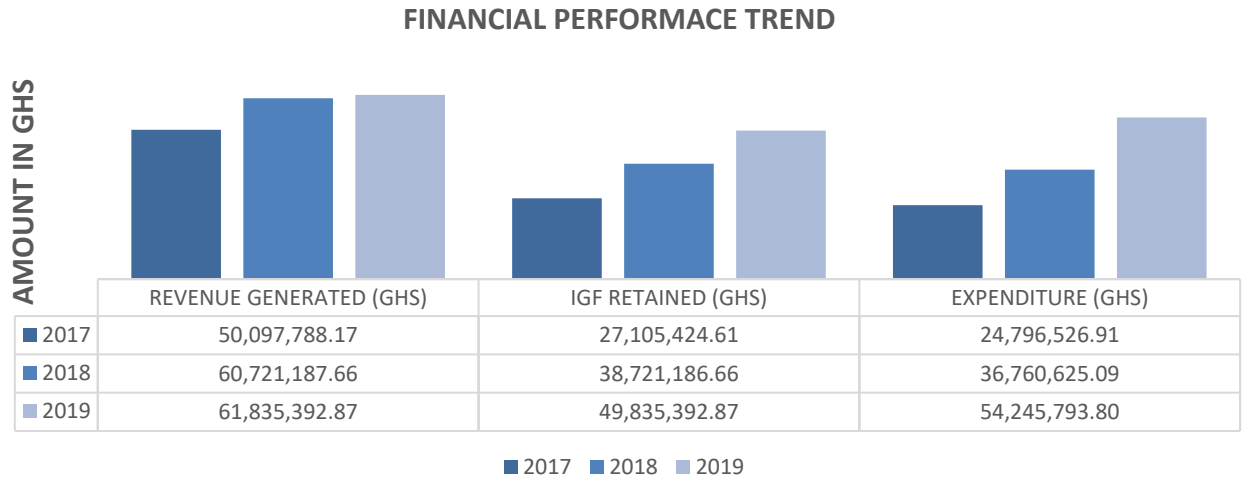


**Figure 3.11-1:** Trend of FDA revenue and expenditure performance for 2017-19.

The FDA's expenditure for 2019 was Fifty-four Million Two Hundred and Forty-Five Thousand Seven Hundred Ninety-Three Ghana Cedis and Eighty Pesewas (GHS54,245,793.80); an increase of approximately 48% compared to 2018 - Figure 3.11-1. This also represents eighty- one percent (81%) of revenue collected. The trend of percentage of expenditure to revenue collected shows the current IGF retention level of 50% still not adequate to support the organisation's expenditure (*Figure 3.11-3*)

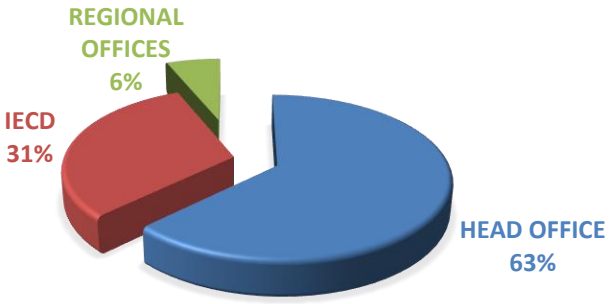

**Figure 3.11-2:** Revenue Collection Distribution for 2019.

In 2019, 52% of the total expenditure was on Goods and Service, 25% on Compensation and 23% on Assets (CAPEX). Comparing with the expenditure in 2018, compensation increased by 34%, Goods and services by 49% and assets by 27%.

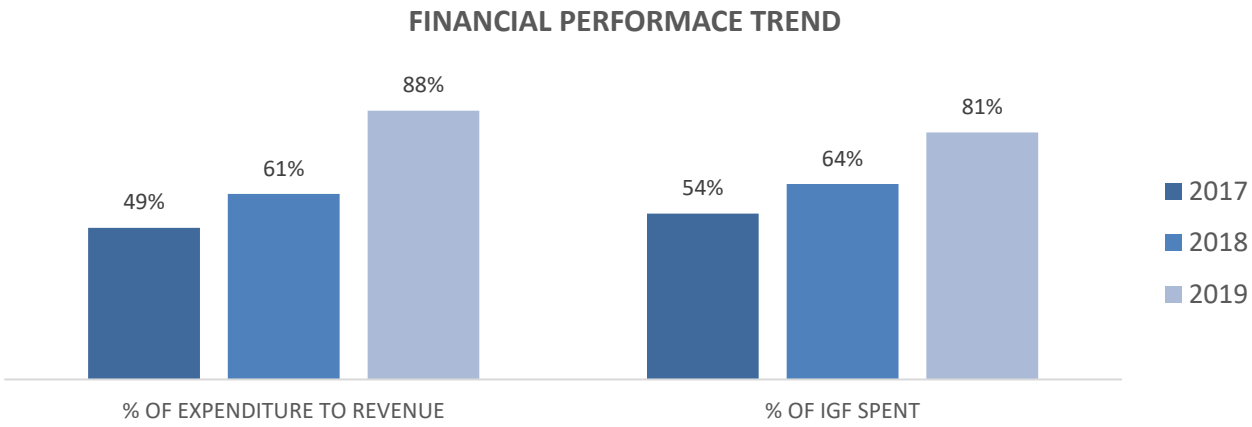


**Figure 3.11-3**: Expenditure trend for internally generated funds (IGF) for 2017-19.

### 3.12 Internal Audit

For the year under review, nine (9) out of the ten (10) audit thrusts were executed by the Internal Audit Department. In 2019, they executed all required financial (revenue and expenditure) audits; this included the Head Office, Tema and KIA Offices, and the nine (9) Regional Offices. At the Head Office, performance audits were conducted for Drug Evaluation and Registration Department, Food Evaluation and Registration Department and the Human Resource Department (Recruitment Audit). All requests received for review of payrolls, payment vouchers and verification of goods supplied to the FDA stores were completed.

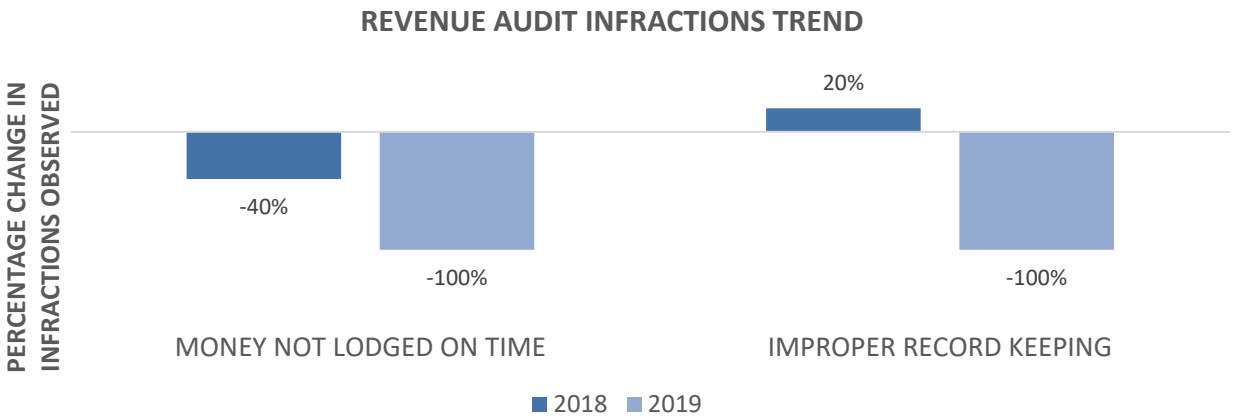

**Figure 3.12-1:** A comparison of revenue infractions observed during the 2019 audits with that of 2018.

On revenue audit infractions, issues relating to non-timely lodging of money was not observed for 2019, representing 100% reduction in its incidence compared to 2018. In respect of maintenance of proper records i.e. receipt book capturing, there were no incidents for the year under review.

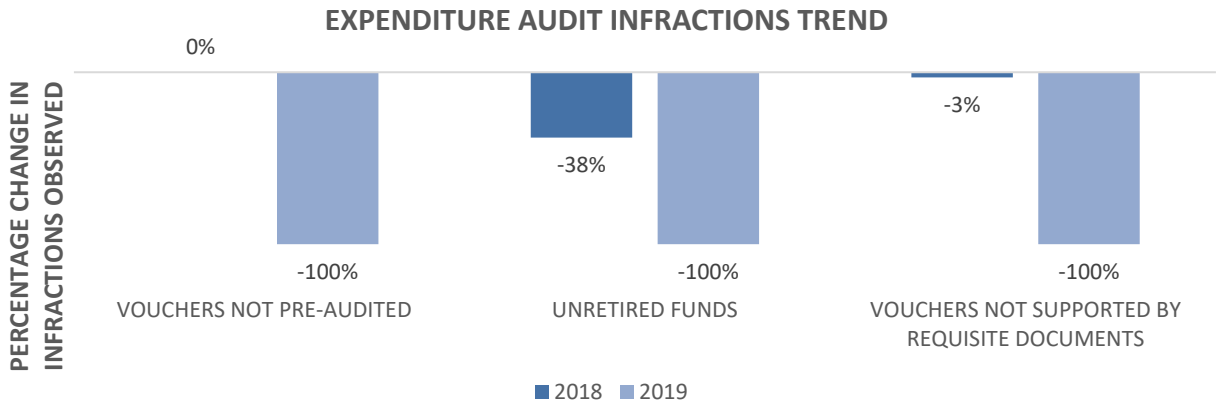


**Figure 3.12-2**: A comparison of expenditure infractions observed during financial audits for 2018 and 2019

On expenditure audits infractions, review of payment vouchers showed all payment vouchers were pre-audited, representing 100% reduction in its incidence compared to 2018. There were no incidents of payment vouchers approved without requisite supporting documents. There were no incidents of unretired funds; this was a further reduction from 2018. Compliance to financial regulations has improved tremendously.

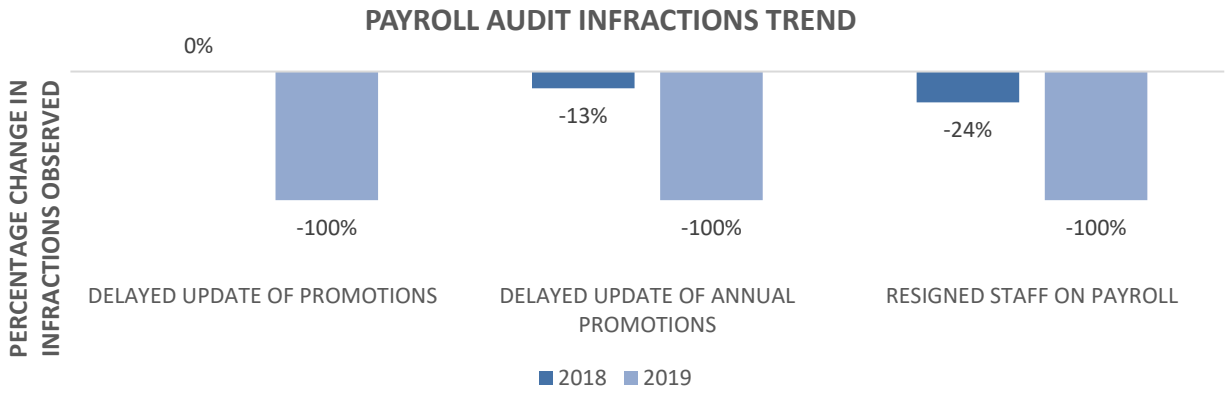


**Figure 3.12-3**: A comparison of payroll infractions observed during payroll reviews for 2018 and 2019.

On payroll audit, there were no infractions observed for promotion updates, annual increment and presence of resigned staff on payroll compared to 2018. No other infractions were observed for the period under review. For the period under review, there were no infractions recorded for revenue,

expenditure and payroll audits. This is a tremendous improvement for the organisation and demonstrates the impact of internal audit on continuous improvement.

## 4 KEY ACHIEVEMENTS FOR 2019

The following are highlights for the year under review:

*Rebranding*

The institution in 2019 undertook series of activities to change the face of the FDA; this included the launch of a new corporate logo, and introduction of an official tagline "Your Well- being, Our Priority". This was done to reflect the new posture of the FDA in response to evolving client and consumer needs, expansion of scope of regulated products, and the quest for continuous improvement to safeguard public health and safety.

*Support for Local Industry*

i. In the bid to support the micro, small and medium scale enterprises (MSMEs) to manufacture safe and quality products, the FDA has secured a grant of Four Hundred and Ninety-Two Thousand Ghana Cedis (GHS492,000.00) from the Skills Development Fund (SDF) to develop a curriculum for a Qualified Supervisor's Course for the food, cosmetic, household chemical substances and herbal medicine manufacturing sector. This will enable MSMEs in these sectors to fulfil requirements of sections 106 and 115 of the Public Health Act, 2012, Act 851.

ii. In support of the local food industry a progressive licensing scheme has been developed to drive continuous improvement in the local food manufacturing sector; implementation of the initiative will commence in 2020. As part of this programme, different categories of licenses will be issued based on the level of compliance of the manufacturer.

iii. To improve retail practices and packaging choices for locally manufactured complimentary foods, the World Food Programme-sponsored Enhanced Nutrition Value Chain project implementation commenced last year. Sampling was successfully completed; the next step involves product testing and analysis of the results.

*National Food Safety Emergency Response Plan*

A stakeholder's conference was held in 2019 as a sequel to one organized in 2018 to complete the development of a national food safety emergency response plan for implementation by the Authority.

*Food Safety Management Regulation*

FDA's food borne disease surveillance indicators have been successfully incorporated into the Integrated Disease Surveillance and Response System of the Ghana Health Service Disease Surveillance Department to enable us collect data on food borne disease incidents across the country.

*Regulation of Street Food Vendors*

In 2018, the FDA signed an MoU with FAO to implement the Healthy Street Food Incentives Project. Implementation was completed in December 2019; about two hundred (200) street vendors have been trained to ensure safer street food for consumers.

*Recruitment and Training*

The FDA recruited 163 new staff in 2019; this has increased the staff strength by 40%. It is hoped that this will further drive our productivity upwards this year. The Human Resource Department facilitated training for about four hundred and forty-seven (447) FDA staff in 2019. This high numbers are attributed to the in-house training programmes initiated by the HR Department.

*Fees & Charges Structure*

A new Fee and Charges structure, which introduces a CIF system of charging fees for imported products has been approved by Parliament. Implementation will commence in January 2020; this revision is expected to provide the FDA with the additional financial resources to enable it deliver on its mandate of protecting public health and safety.

*Procurement of Operational Vehicles*

The FDA has procured eleven (11) pickups and six (6) small engine capacity (1.1 L) vehicles; these will be delivered by end of Q1 2020. This increase in the vehicle fleet would enhance enforcement activities. According to the Head of Procurement as financial resources become available, an additional fourteen (14) vehicles will be procured for operational activities.

*Quality Risk Management Tool for Inspections*

To enable the FDA use its limited resources efficiently, a quality risk management tool for risk-based inspection has been developed by the Drug Inspectorate Department. This will enable the FDA to focus on high risk products and manufacturers for inspection planning

and scheduling for pharmaceutical industries.

*Formation of Joint Malaria Vaccine Committee*

In support of the Malaria Vaccine Implementation Programme, the FDA constituted a Joint Malaria Vaccine Committee (JMVC). These independent experts reviewed safety information from the Malaria Vaccine Implementation Programme (MVIP) and advised the FDA accordingly. The FDA also provided training for the members of the JMVC as well health professionals in the Regions participating in the MVIP.

*Launch of Med Safety App*

The Med Safety App was launched in June 2019; it enables patients and healthcare professionals report adverse effects arising from the use of medical products. It will also provide medical product safety information to users of the app.

*New FDA Offices & Land Acquisition*

The office complex at Tema is now 99% completed and would be occupied by end of Q2 2020. This will alleviate the office space constraints currently being experienced at the Head Office. A new office building has been rented for the Bono Regional Office. The FDA has initiated the acquisition of lands for the Northern, Bono East, and Central Regional Offices.

*ICT Infrastructure Upgrade*

FDA's ICT infrastructure upgrade is in progress; this will bring relief to staff in respect of internet services including the deployment of Wi-Fi at the Head Office and enhance the use of the official corporate mailing systems.

*Acquisition of New Certificate Software*

A new certificate software has been developed; it has enhanced security features and will allow authentication of issued certificates by consumers on the FDA website.

*Public Education and Communication Activities*

Our following on social media presence has greatly improved on WhatsApp, Facebook, Instagram and Twitter. It has transformed the way FDA interacts with consumers and is delivering remarkable results.

*Recognition and Awards*

At the 2019 Ghana Accountancy and Finance Awards, the Finance Department of the FDA received the award for the Accounts and Finance Team of the year. The CEO of FDA Mrs. Delese A. A. Darko continued to attract attention to her excellent leadership at the FDA and within the regulatory space as she received awards in recognition of her contribution to the developments in Health and Business in Ghana:

i. Female Business Leader of the year – Delese Mimi Darko (Ghana Business Standard Awards 2019)
ii. Exhibitor CEO - Delese Mimi Darko (4th Ghana CEO summit)
iii. Outstanding Leadership Award – Delese Mimi Darko (Ghana Pharma Awards)
iv. Excellence in Health – Delese Mimi Darko (Ghana Women of the year Honours)
v. Special Recognition Award- Delese Mimi Darko (Advertising Association of Ghana)

*ISO Implementation*

The FDA laboratory transitioned from ISO/IEC 17025:2005 accreditation to the ISO/IEC 17025:2017; the Lab is currently accredited to 40 tests, the highest scope in Africa. The FDA Head Office retained its ISO 9001:2015 certification after a successful surveillance audit; the scope has been expanded to the Regional Offices; implementation has commenced with the Ashanti and Volta Regions.

*WHO Global Benchmarking Tool (GBT)*

The FDA participated in the WHO GBT for Regulatory System Strengthening Programme; the experience helped to further strengthen the administrative and operational systems of the FDA. The classification is expected after the WHO team visit in April 2020; it is anticipated that FDA would be classified as a Maturity Level 3 National Regulatory Authority. That will place the FDA on the WHO list of reference National Regulatory Agencies.

## 5 CHALLENGES

As the FDA awaits the delivery of operational vehicles and additional computers and accessories for 2020, these continue to affect the effectiveness and efficiency of the enforcement activities. The rising cost of rentals across the country for office accommodation continues to increase the cost of FDA's operations.

The FDA is required by the Ministry of Finance to retain 50% of IGF generated. This affects FDA's ability to provide the requisite services to its clients as 50% of service charges is retained by Government.

## 6 CONCLUSION

The performance of the FDA in respect of its regulatory functions of product registration, facility licensing, market surveillance, import and export control, product testing, safety monitoring and public education increased compared to last year's performance. This follows the trend observed in 2017 and 2018. There was, however, an 18% decrease in the total number of inspections particularly for the food industry attributed to constraints with transportation. There is opportunity to improve efficiency of the Authority's operations, such as the percentage of product applications processed, percentage of licensing inspections conducted, percentage of submitted products tested, among others. The provision of the following resources: vehicles, computers, application software (including online application system) and laboratory equipment, consumables, and materials will further enhance the performance of the FDA.

## 7 WAY FORWARD

The FDA will continue to intensify core regulatory activities of product registration, facility licensing, market surveillance, product quality testing, clinical trials and safety monitoring, control of tobacco and substance of abuse and related auxiliary functions. Additionally, the organization will

i. Continue to support the local industry through capacity building and will pursue donor support in this regard towards the strengthening of same.
ii. Pursue financial clearance for recruitment of additional staff.
iii. Continue to work with Public Services Commission on the approval of the FDA's new organizational Structure.
iv. Continue to work with the Fair Wages and Salaries Commission on the approval of the FDA's Conditions of Service.
v. Procure additional logistics – vehicles and ICT equipment to enhance operational efficiency.
vi. Work with the Ministry of Finance to categorise the source of IGF into service and non-service charges; to allow us retain fully service charges to enable the FDA fulfil its obligations to its clients.
vii. Move some of its staff from the Head Office and Tema Harbour Office into the FDA Office complex at Tema.
viii. Maintain the respective ISO accreditation for the FDA Laboratory and the Head Office and expand scope of accreditation to the Ashanti and Volta Regional Offices.
ix. Achieve maturity level 3 WHO listed National Regulatory Agency for Medicines regulation.
x. Implement the fee and charges schedule based on %CIF of consignments at the Port of entry.
xi. Win public confidence through increased engagement and responsiveness to their needs.

## 8 ANNEX I – LIST OF GOVERNING BOARD MEMBERS

| FDA GOVERNING BOARD MEMBERS | | | |
|---|---|---|---|
| | **NAME** | **DEPARTMENT/DIVISION** | **POSITION** |
| 1 | Dr. Sammy Ohene | Head of Psychiatry Department University of Ghana Medical School | Chairman |
| 2 | Mrs. Delese A. A. Darko | Chief Executive Officer | Member |
| 3 | Dr. Alhassan Emil Abdulai | Senior lecturer & Head of Department-Oral and Maxillo-Facial Surgery, School of Medicine & Dentistry. University of Ghana. Accra. | Member |
| 4 | Joyce Dontwi (Dr.) | Director – Veterinary Services Directorate | Member |
| 5 | Nana. K. Obiri | National Organiser- Ghana Federation of Traditional Medicine Practioners Association (GHAFTRAM) | Member |
| 6 | Pharm. Audu Rauf | Registrar-Pharmacy Council | Member |
| 7 | Prof. Alex Dodoo | Executive Director Ghana Standard Authority | Member |
| 8 | Kofi Bobi Barimah (Dr.) | Ag. Executive Director Centre for Plant Medicine Research | Member |
| 9 | Mrs. Anna Pearl Akiwuni-Siriboe | Chief State Attorney Ministry of Justice and Attroney General's Department | Member |
| 10 | Dr. Mary Obodai | Principal Research Scientist Food Research Institution | Member |

## 9 ANNEX II – LIST OF STRATEGIC MANAGEMENT MEMBERS

| STRATEGIC MANAGEMENT MEMBERS | | |
|---|---|---|
| | **NAME** | **DEPARTMENT/DIVISION** |
| 1 | Mrs. Delese A. A. Darko | Chief Executive Officer |
| 2 | Mr. Seth K. Seaneke | Ag. Deputy Chief (DRID) |
| 3 | Mrs. Akua O. Amartey | Ag. Deputy Chief (MDCHCD) |
| 4 | Mr. Jones Ofosu | Head, Administration |
| 5 | Mr. Nicholas Agbomadzi | Head, Finance |
| 6 | Mr. Eric Karikari-Boateng | Head, Laboratory Services |
| 7 | Mr. Isaac Dapaah | Head, Projects Research & Mgt Info. Systems |
| 8 | Mr. Solomon Agampim | Head, Import & Export Control |
| 9 | Mr. Edem Kofi Kugbey | Head, Internal Audit |
| 10 | Ms. Mary Mintah | Head, Human Resource |
| 11 | Mrs. Cynthia Dapaah Ntow | Head Legal |
| 12 | Mr. James Lartey | Head Communications and Public Education |

## 10 ANNEX III – LIST OF MIDDLE LEVEL MANAGEMENT MEMBERS

| MIDDLE LEVEL MANAGEMENT | | |
|---|---|---|
| | **NAME** | **DEPARTMENT/REGION** |
| 1 | Mr. Joseph Yaw-Bernie Bennie (Chairman) | Medical Devices Department |
| 2 | Mrs. Harriet Ofori-Antwi (Secretary) | Food Microbiology Unit |
| 3 | Mrs. Faustina Atupra | Agro Products and Biosafety Department |
| 4 | Mr. Percy Adomako Agyekum | Food Evaluation and Registration Department |
| 5 | Mr. Roderick Daddey Adjei | Food Market Surveillance Department |
| 6 | Ms. Maria Lovelace-John | Food Inspectorate Department |
| 7 | Mr. Ebenezer Kofi Essel | Food Industrial Support Department |
| 8 | Mrs. Jocelyn Adeline Egyakwa-Amusah | Food Safety Management Department |
| 9 | Mr. Emmanuel Nkrumah | Cosmetics & Household Chemical Substances Department |
| 10 | Mr. Geoffrey Victor Arthur | Medical Devices, Cosmetics & Household Chemical Substances Inspectorate Department |
| 11 | Mr. Matthew Gyang-Nkum | Medical Devices, Cosmetics & Household Chemical Substances Market Surveillance |
| 12 | Mr. Samuel Asante-Boateng | Drug Evaluation and Registration Department |
| 13 | Mr. Thomas Amedzro | Drug Inspectorate Department |
| 14 | Mr. Vigil Edward Prah-Ashun | Drug Market Surveillance Department |
| 15 | Mrs. Olivia Agyekumwaa Boateng | Tobacco & Substance of Abuse Department |
| 16 | Mr. Emmanuel Yaw Kwarteng | Herbal Medicines Department |
| 17 | Mrs. Mercy Owusu-Asante | Drug Industrial Support Department |
| 18 | Dr. Edwin Nkansah | Biological Products Department |
| 19 | Mr. George Sabblah | Safety Monitoring Department |
| 20 | Mrs. Yvonne Adu Boahen | Clinical Trials Department |
| 21 | Mrs. Naana Afrakoma Yawson | Procurement Department |
| 22 | Mrs. Nora Narkie Terlabie | Ashanti Regional Office |
| 23 | Mr. John Odai-Tettey | Central Regional Office |
| 24 | Mr. Gorden Akurugu | Volta Regional Office |
| 25 | Mr. Abu Sumaila | Western Regional Office |
| 26 | Ms. Akua Amponsaa Owusu-Antwi | Bono Regional Office |
| 27 | Mr. Samuel Kwakye | Eastern Regional Office |

| MIDDLE LEVEL MANAGEMENT | | |
|---|---|---|
| | **NAME** | **DEPARTMENT/REGION** |
| 28 | Mr. Martin Kusi | Northern Regional Office |
| 29 | Mr. Sebastian Hotor | Upper East Regional Office |
| 30 | Mr. Albert Ankomah | Upper West Regional Office |
| 31 | Mr. Cheetham Mingle | Food Physico-Chemical Unit, LSD |
| 32 | Mr. Ernest Delali Afesey | Drug Physico-Chemical Unit, LSD |
| 33 | Mrs. Delali Dei-Tutuwa | Pharmaceutical Microbiology Unit, LSD |
| 34 | Mr. Joseph Ofosu Siaw | Quality Assurance Unit, LSD |
| 35 | Mrs. Maureen Lartey | Animal Products Department |
| 36 | Mr. Roland Sefakor | Medical Devices Unit, LSD |
| 37 | Mr. Ishmael Larkai | Cosmetics and Household Chemicals Unit, LSD |
| 38 | Mr. Kwame Dei Asamoah-Okyere | Monitoring and Evaluation Division |
| 39 | Mr. Jacob Amoako-Mensah | Import Export Control Department |