REPUBLIC OF GHANA

2009
ANNUAL REPORT

FOOD AND DRUGS BOARD

.....Working for your safety

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FIGURES

TABLES

ACRONYMS AND ABBREVIATIONS

ADRs - Adverse Drug Reactions

CEPS	-	Customs Excise and Preventive Service
CID	-	Criminal Investigation Department
CMS	-	Central Medical Stores
FDB	-	Food and Drugs Board
FDL	-	Food and Drugs Law
FSMU	-	Food Safety Management Unit
FPMSU	-	Food Post Market Surveillance Unit
FPIU	-	Food Premises Inspection Unit
GAIN	-	Global Alliance for Improved Nutrition
GAP	-	Good Agricultural Practice
GCMS	-	Ghana Customs Management System
GCNet	-	Ghana Community Network Limited
GCP	-	Good Coldstore Practices
GHP	-	Good Hygiene Practice
GM	-	Genetically Modified
GMP	-	Good Manufacturing Practices
GWP	-	Good Warehouse Practice
HACCP	-	Hazard Analysis and Critical Control Point
IECD	-	Import and Export Control Department
ICT	-	International Competitive Tender
ISO	-	International Standard Organization
KNUST	-	Kwame Nkrumah University of Science and Technology

NCB	-	National Competitive Bidding
NFFA	-	National Food Fortification Alliance
NMCP	-	National Malarial Control Programme
PNDC	-	Provisional National Defence Council
PNDCL	-	Provisional National Defence Council Law
PRMIS	-	Projects, Research and Management Information System
QAMSA	-	Quality of Anti-malarial Survey Assessment
TAC	-	Technical Advisory Committee
MOFA	-	Ministry of Food and Agriculture
U.K	-	United Kingdom
USI	-	Universal Salt Iodation
WHO	-	World Health Organization

EXECUTIVE SUMMARY

The year 2009 saw the continuation of work to consolidate the institutional framework for the establishment of the Food and Drugs Board (FDB) as a Government regulatory body responsible for the control of the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemical substances under the Food and Drugs Law 1992 (PNDCL 305B) and its amendment Act 523, 1996. The passage of Tobacco Control Bill and the revision of the Food and Drugs Law are still pending at the Parliament. Other policies and guidelines aimed at strengthening the FDB to deliver on its mandate were put in place. These included the guidelines and documents for food and drugs activities and the fee schedule of the FDB. An inventory of other policies and guidelines already developed, which have implications for the operations of the FDB were initiated and steps were taken to review them.

During the year, a range of activities including Consumer Awareness programmes, and Good Manufacturing Practices (GMP) training programmes were outlined to support industry and to protect public health and safety.

Applications for the registration of drugs and food and premises inspections increased significantly during the year. There was an improvement in the operations of the Zonal Offices over the previous year. The FDB continued its regulatory control of the exportation of palm oil to the European Union. The FDB also continued its decentralisation policy by opening new office at Akanu for the implementation of its mandate.

1. INTRODUCTION

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

1.1 Background of Food and Drugs Board

Before 1990, the control of drugs and the practice of pharmacy profession were under the Pharmacy and Drugs Act (Act 64), 1961. In 1990, the Provisional National Defence Council (PNDC) passed the Narcotics Drugs Control, Enforcement and Sanctions Law (PNDCL 236). This law established the Narcotics Control Board to deal with the rising incidence of drug abuse in the country and threatening dimensions that illicit drug dealing had taken internationally.

In 1992, the PNDC separated the control of drugs other than narcotics from the practice of Pharmacy.

The Food and Drugs Law, 1992 (PNDCL 305B) was then enacted to control the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemical substances. The Pharmacy Act 489 was subsequently passed in 1994 to establish the Pharmacy Council to control the practice of the Pharmacy profession and the registration of Pharmacists. Although the Food and Drugs Law was passed as far back as 1992, it was not until 26th August 1997 that the first Board was inaugurated.

The Food and Drugs Board is under the control and supervision of the Minister responsible for Health.

1.2 Functions of the Board

The functions of the Board as spelt out by law (PNDCL 305B) are as follows:

The Board shall advise the Minister of Health on all matters relating to the administration and implementation of the Law.

Without prejudice to the above, the Board shall

- *advise the Minister on measures for the protection of the health of consumers;*
- *in co-operation with the Ghana Standards Board, ensure adequate and effective standards for food and drugs;*
- *monitor through the District Assemblies and other agencies of state compliance with this Law;*
- *advise the Minister on the preparation of effective regulation for the full implementation of the provisions of the Law;*
- *perform the functions assigned to it under this law*

1.3 Mandate

The Food and Drugs Law of 1992, (PNDCL 305B), which established the Food and Drugs Board, put the control, the manufacture, importation, exportation, distribution, use and advertisements of food, drugs, cosmetics, medical devices and household chemicals under the purview of the Board with respect to ensuring their safety, quality and efficacy.

1.4 Vision

The vision of the Food and Drugs Board is to become a centre of excellence in food and drug regulatory affairs on the African continent.

1.5 Mission Statement and Goals

The Food and Drugs Board aims to implement the appropriate regulatory measures to achieve the highest standards of safety, efficacy, and quality for all food, drugs, cosmetics, household chemical substances and medical devices (hereinafter referred to as products) locally manufactured, imported, exported, distributed, sold, or used, to ensure the protection of the consumer as envisaged by the law regulating food and drugs in force in Ghana.

To realize this mission, the Food and Drugs Board has set for itself the following goals:

The FDB shall:

- *Advise the Minister of Health on measures to protect the health of the consumer.*

- *Recruit qualified staff and ensure their training, development and maintenance for optimal productivity and quality service delivery.*
- *Ensure that Legislative Instruments are passed for the laws and guidance of its clients.*
- *Develop and implement a well researched communications strategy to promote the functions of the Food and Drugs Board and matters relating to the health of the consumer under the Food and Drugs Board's contributions to safety and efficacy.*
- *Ensure that product information and advertisement are not misleading or deceptive nor contain references to diseases for which advertisement is prohibited.*
- *Ensure that all local manufacturers of products are licensed and that their operations conform to current codes of Good Manufacturing Practices (GMP).*
- *Ensure that all products locally manufactured, imported, and/or exported are registered to assure their safety, quality and efficacy.*
- *Collaborate with other governmental and non-governmental bodies, the district and municipal assemblies to enable optimal performance of its functions.*
- *Undertake research and analysis to enable the fulfilment of its obligations to the nation.*
- *Develop an organizational structure with financial, information technology and human resource facilities that encourage selfdevelopment, responsibility and empowerment of staff to meet the functions of the Food and Drugs Board.*
- *Have well branded, comprehensive, distinctive and high quality operations throughout the nation.*
- *Establish, maintain, monitor and update standards of products.*

1.6 The Governing Board

The Food and Drugs Law, 1992 (PNDCL 305B) and Food and Drugs Amendment Act 523, 1996 provide for a management structure spear-headed by a Governing Board appointed by the President of the Republic of Ghana. In March 2009, a new Chief Executive in the name of Dr. Stephen Kwabena Opuni was appointed to Head the Food and Drugs Board from the Komfo Anokye Teaching Hospital, Kumasi

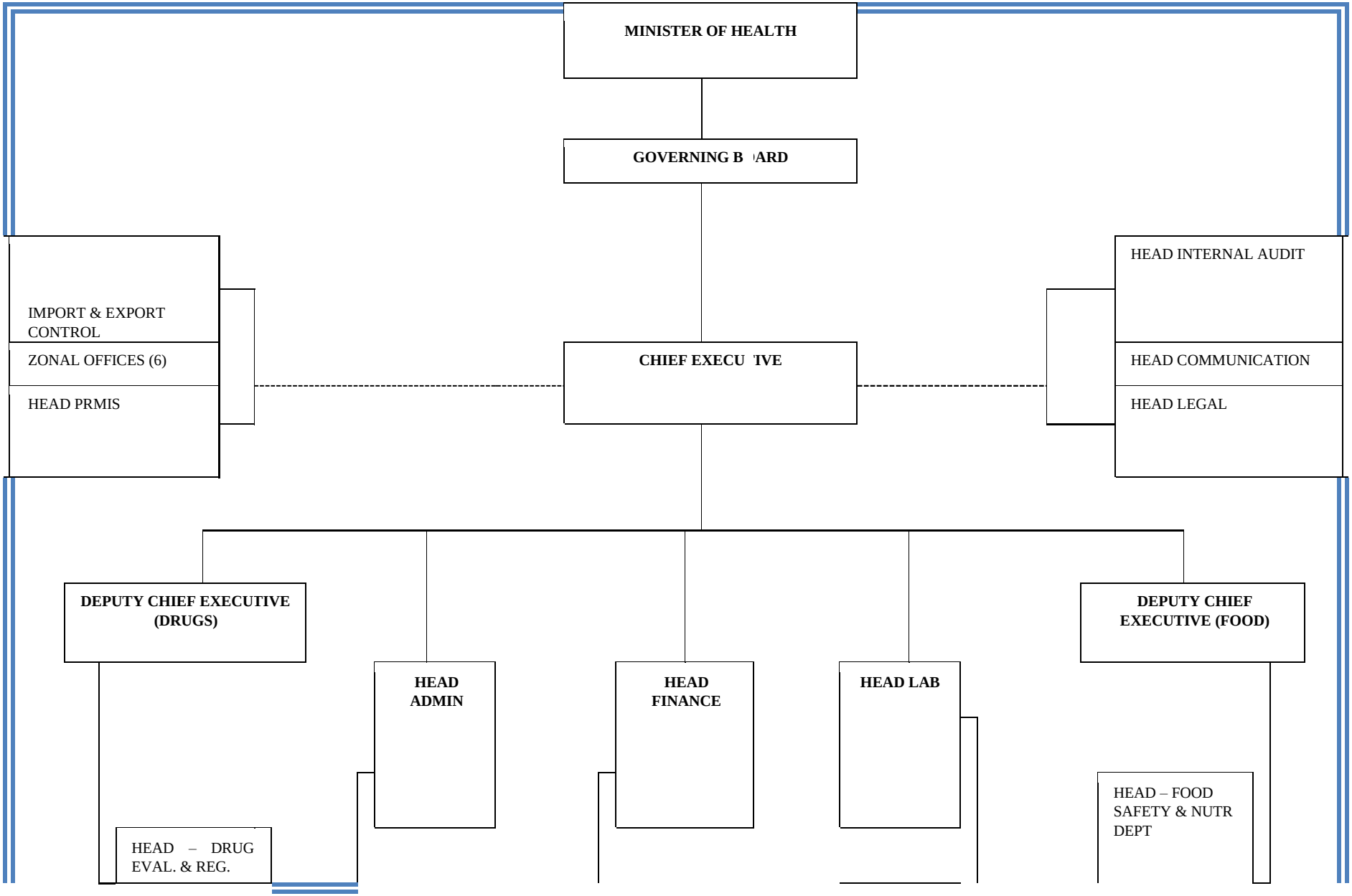
The following are the current members of the Governing Board of the Food and Drugs Board:

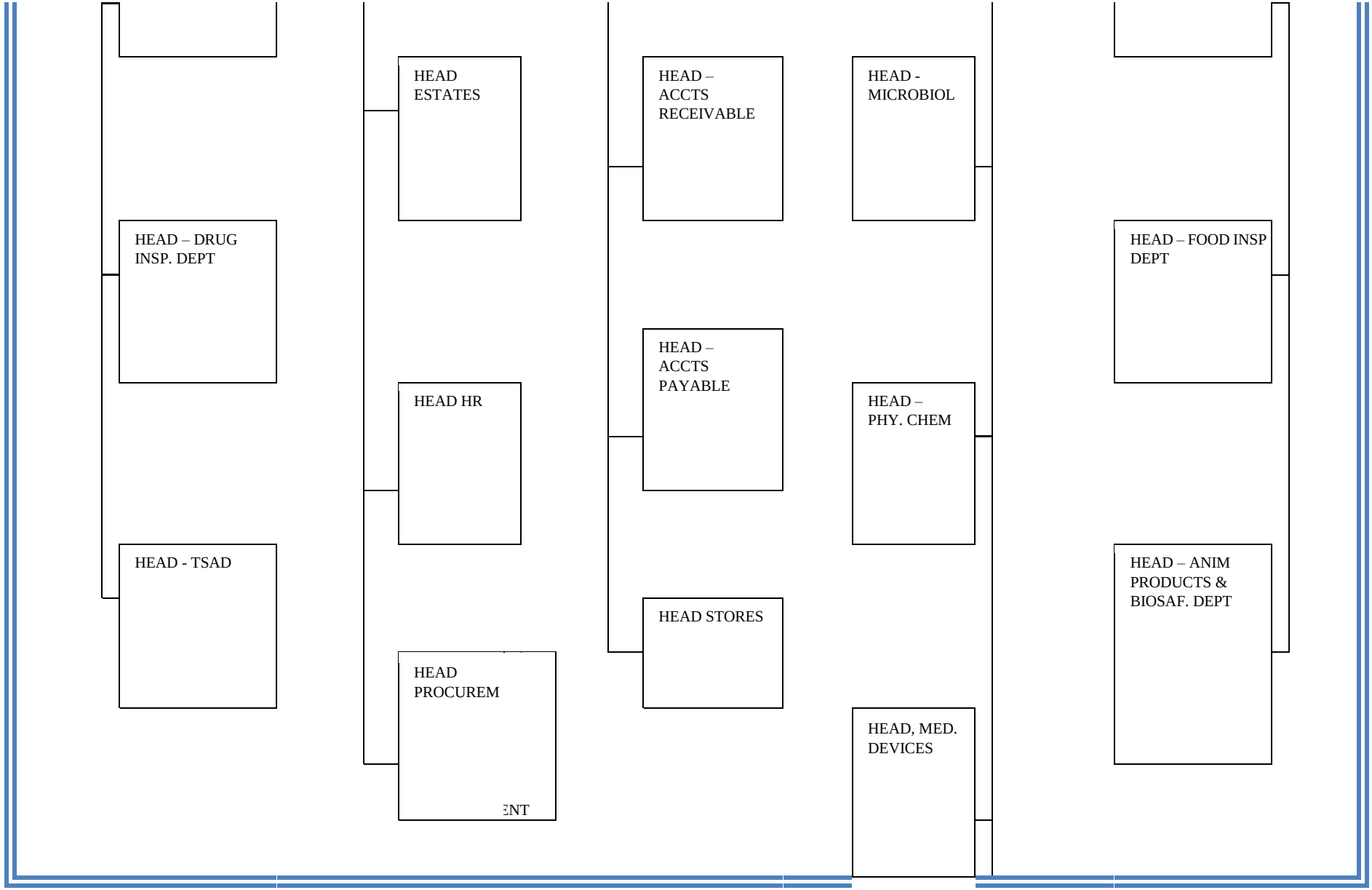
1. Mr. T.C Corquaye	Chairman, Government Representative.
2. Dr. Stephen K. Opuni	Chief Executive, Food and Drugs Board
3. Mr. J.A. Pwanmang	Rep. Environmental Protection Agency
4. Mr. Joseph Nyoagbe	Registrar, Pharmacy Council
5. Dr. Paa Nii Johnson	Director, Food Research Institute
6. Mr. Alfred Yeboa Tetebo	Fisheries Dept., Ministry of Food and Agriculture
7. Dr. Enoch Mensah Koney	Director, Veterinary Services
8. Mr. Kwaku Amoo-Baffoe	Director, Crop Services, MOFA
9. Dr. George Ben Crentsil	Executive Director, Ghana Standards Board.
10. Dr. Kwaku Tano-Debrah	Dept of Nutrition & food Science University of Ghana
11. Ms. Grace Issahaque	Rep Attorney General's Department.
12. Dr. Opoku	Rep Medical and Dental Council
13. Mrs. Ribeiro	Consumer Representative
14. To be nominated	Consumer Representative
15. Mr. Kenneth Danso	Rep. Ghana Association of Traditional Healers

The Food and Drugs Board has been without a Governing Board since October 2007 to December 2008.

1.7 The Organisational Structure

The current organogram of the FDB is indicated on page 5.


MINISTER OF HEALTH
GOVERNING B ARD
IMPORT & EXPORT CONTROL
ZONAL OFFICES (6)
HEAD PRMIS
CHIEF EXECU IVE
HEAD INTERNAL AUDIT
HEAD COMMUNICATION
HEAD LEGAL
DEPUTY CHIEF EXECUTIVE (DRUGS)
HEAD ADMIN
HEAD FINANCE
HEAD LAB
DEPUTY CHIEF EXECUTIVE (FOOD)
HEAD – DRUG EVAL. & REG.
HEAD – FOOD SAFETY & NUTR DEPT


HEAD – DRUG INSP. DEPT
HEAD - TSAD
HEAD ESTATES
HEAD HR
HEAD PROCUREM
ENT
HEAD – ACCTS RECEIVABLE
HEAD – ACCTS PAYABLE
HEAD STORES
HEAD - MICROBIOL
HEAD – PHY. CHEM
HEAD, MED. DEVICES
HEAD – FOOD INSP DEPT
HEAD – ANIM PRODUCTS & BIOSAF. DEPT

In summary, the FDB as a national regulatory body has the responsibility for the regulatory control of manufacture, import, export, distribution, advertisement and product information for food, drugs, cosmetics, medical devices and household chemicals. This is a very critical role, as misbranding, substandard and/or counterfeit, as well as unsubstantiated product information has very grave consequences on public health and serious implications for healthcare delivery. The FDB, since August 1997, has been pursuing various specific objectives to address issues on regulatory control of products as stated above.

The ensuing sections deal with the summaries of achievements in 2009.

2.0 DRUGS DIVISION

The Drug Division contributes to the attainment of the functions of the Food and Drugs Board for safeguarding public health by ensuring that all medicines on the market meet appropriate standards of safety, efficacy, and quality. These functions are carry out by evaluating all information submitted in the registration dossiers, pre-registration inspection, and drug quality analysis reports.

The Division also evaluates and registers veterinary medicines to promote and protect animal health and to ensure safe animal products for human consumption.

The activities of the Division are carried out by three specialized departments and supported by six operational units.

2.1 Drug Evaluation and Registration Department

The Drug Evaluation and Registration Department of the Food and Drugs Board is made up of the following operational units:

- Medicine and Vaccines Evaluation and Registration Unit
- Safety Monitoring Unit
- Herbal Medicine Unit
- Cosmetic, Household Chemicals and Medical Devices Unit

2.1.1 Medicine Evaluation and Registration Unit

The main functions of Medicine Evaluation and Registration Unit are:

- Registration of drug products and issuance of certificates:
  The Assessment of applications for the registration of medicines and vaccines products involves the following:
- Evaluation of dossiers submitted for registration to ensure that application forms are properly completed and the requisite information and certificates are duly submitted.

- Ensuring that information provided on packages and package inserts are correct and adequate to enable the FDB take the appropriate decision.
- Active maintenance of SIAMED database (WHO drug registration application software).
- To conduct product registration exercise to review applications.

During the year under review, 1,047 product applications were submitted to the Medicines Evaluation and Registration Unit. This total number was made up of 803 imported allopathic drugs (human), 101 locally manufactured allopathic drugs (humans), 31 imported allopathic drugs for veterinary use and 112 food supplements. 524 applications were submitted for product re-registration. This figure was made up of 490 imported allopathic drugs for humans, 7 veterinary applications, and 27 food supplements. Table 1 and 2 give the summaries of applications received for registration and reregistration respectively, during the year under review.

Table 1: Summary of applications received and registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	803	101	367	89
Veterinary Drugs	31	-	60*	-
Food Supplements	112	-	101	-
Vaccines	-	-	-	-
Total	**946**	**101**	**528**	**89**

*Excess products registered were application brought forward from 2008
Source: 2009 Registration of Medicines Activities

Table 2: Summary of applications received for re-registration

Product Type	**Applications Received**		**Number Re-registered**	
	Foreign	Local	Foreign	Local
Allopathic Drugs (Human)	401	89	290	116*
Veterinary Drugs	7	-	6	-
Food Supplements	27	-	17	-
Vaccines	-	-	-	-
Total	**435**	**89**	**313**	**116**

*Excess products registered were applications brought forward from 2008 Source:
2009 Re-registration of medicines Activities

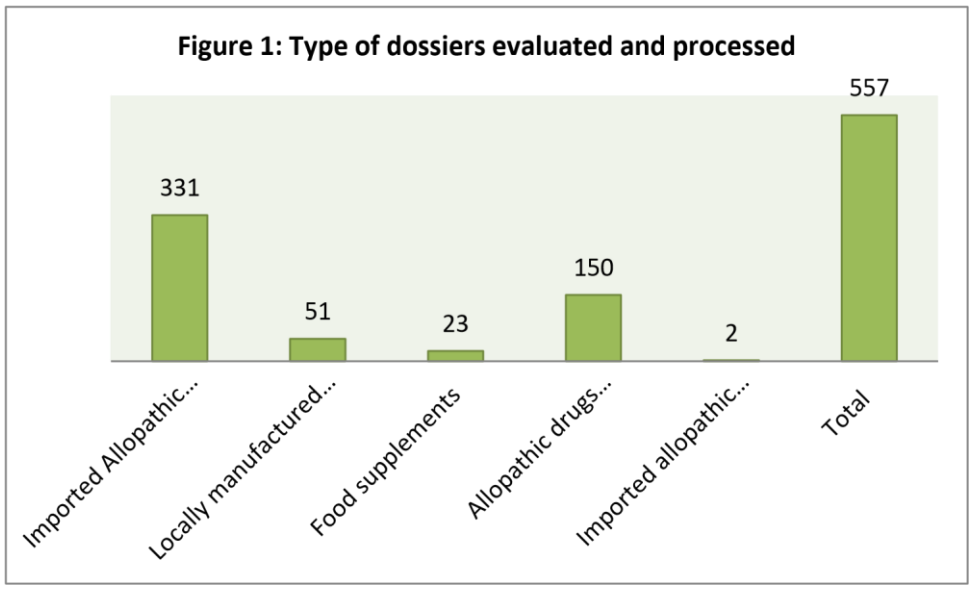
2.1.1.1 Product Registration and Document Reviews

In the year 2009, eight (8) dossier evaluations and four (4) product registration meetings were held. The following are the details of the documentation, which were evaluated at the dossier evaluation meetings.

Table 3: Product Registration and Document reviews

TYPE OF DOCUMENT	NUMBER EVALUATED
Imported Allopathic Drug Registration (for Human)	331
Locally manufactured allopathic Drugs Registration (for Humans)	51
Food supplements	23
Allopathic drugs additional documentation	150
Imported allopathic medicines registration (veterinary)	2
Total	**557**

Source: 2009 Registration Documentation



Source: 2009 Dossiers Evaluated

2.1.2 Cosmetics, Medical Devices and Household Chemical Substance Unit

The principal functions of the Unit are:

- Evaluation of documents related to all cosmetics, medical devices and household chemicals substances.
- Registration of cosmetic products, medical devices and household chemical substances.

During the year under review, a total number of four hundred and fifty-four (454) applications were submitted for registration. Three hundred and thirty-six (336) of the applications were new applications and one hundred and eighteen (118) were applications for re-registration. Out of the total number of application received, two hundred and fifty seven (257) applications were for cosmetics, sixty nine (69) products pending approval from the previous year were approved in addition to two hundred and fifty seven (257) products. The total number of applications submitted for household chemical substances were fifty nine (59), of which forty seven (47) were given approval and twelve (12) were deferred. One hundred and thirty eight (138) applications for medical devices were received. One hundred and twenty five (125) were given approval and thirteen (13) were deferred.

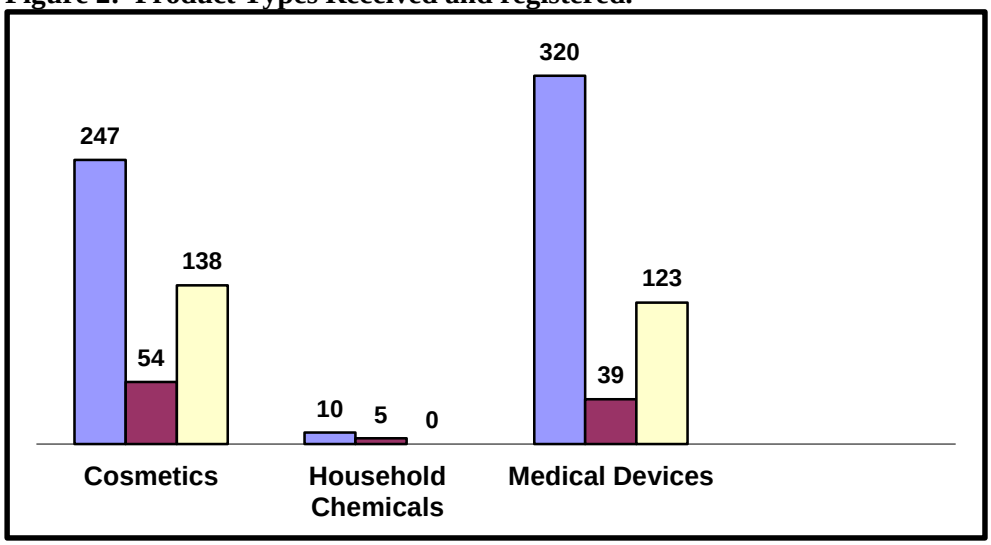
Table 4 and Figure 2 respectively, show the number of products received and registered during the year under review.

Table 4: Summary of types of products received and registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Cosmetics	247	10	320	6
Household Chemicals	54	5	39	8
Medical Devices	138	-	123	2
Total	**439**	**15**	**482**	**16**

* 73 and *3 products pending approval from the previous quarters were approved in addition to total received and approved in 2009

Figure 2: Product Types Received and registered.



Source: 2009 Registration of Activities

2.1.3 Herbal Medicine Unit

The main functions of the Herbal Medicine Unit are:

- Registration, processing and evaluation of all herbal medicine applications.
- Evaluation of toxicological and clinical information as well as therapeutic data submitted from Centre for Scientific Research into Plant Medicine, Mampong-Akuapim, Noguchi Memorial Institute for Medical Research, Legon-Accra, Faculty of Pharmacy, Kwame Nkrumah University of Science and Technology (KNUST) -Kumasi, and Department of Pharmacology, Korle-Bu Teaching Hospital
- Issuance of product registration number, which is valid for one (1) year in case of locally manufactured products and three (3) years for imported herbal drugs.

During the year under review a total number of two hundred and sixty seven (267) applications were received and two hundred and twenty four (224) products approved. The

drop in number of applications was as a result of the increase in the registration fee that took effect in August 2009.

Table 5: Summary of herbal products received and registered

	Applications Received		**Number Registered**	
	Foreign	Local	Foreign	Local
Registered Herbal Products	59	89	60	65
Re-registered Herbal Products	14	109	13	86
Total	**73**	**198**	**73**	**151**

Source: 2009 Registration Activities

2.1.4 Safety Monitoring Unit

The functions of the Safety Monitoring Unit are as follows:

- To collaborate with the Drug Post-Market Surveillance Unit to monitor Adverse Drug Reactions (ADRs).
- Promotion of spontaneous reporting of Adverse Drug Reactions (ADRs)
- Promotion of reporting on adverse effects following immunisation in the country.
- Assessment and validation of completed ADR case report forms and onward submission to the World Health Organisation (WHO) collaborating Centre for International Drug Monitoring known as Uppsala Monitoring Centre.
- Communication of drug-related problems and recommend regulatory actions to stakeholders.
- Pharmacoepidermiological studies and other research activities (through designated research centres).
- Maintaining contacts with international institutions working in Pharmacovigilance such as WHO Department of Essential Drugs and Medicines Policy (Geneva), and The Uppsala Monitoring Centre (Sweden).
- Organise Technical Advisory Committee (TAC) on safety monitoring Serve as Product Information Centre.
- To collaborate with local stakeholders and professional associations such as Pharmaceutical Society of Ghana.
- Collection, collation and maintenance of National database for adverse reaction and events reports

Activities carried out in 2009 include the following:

- Four (4) Technical Advisory Committee meeting
- Fourteen (14) Sensitization lectures
- Routine Collection, collation and maintenance of the national database for adverse reaction and events reports.

Table 6: Summary of activities conducted by Safety Monitoring Unit

Activities	Number	Remarks
Safety Reports Received	290	
ADR Reports Received	156	
Suspected Product Quality Reports	2	
AEFI Reports Received	15	
Reports forwarded to TAC	171	
Reports completely assessed by TAC	171	
Reports from Anti-malarial Cohort Event Monitoring (CEM): • Koforidua Regional Hospital • Police Hospital	1288 Patients 292 Pregnant Women	□ The most ADR reported is general weakness □ The most common reported ADR is vomiting
Reports committed by the FDB to W.H.O Pharmacovigilance (Vigiflow)	269	

Source: 2009 Safety Monitoring Activities

2.1.4.1 Training/Workshop Hospitals/Institutions

The Unit organised ten (10) Pharmacovigilance training for four departments at the Korle-bu Teaching Hospital, four departments at the 37 Military Hospital, Ridge Hospital staff members and 4th year Nursing Students at the University of Ghana, Legon.

The Unit also participated in Ghana Health Service training workshop for the Drugs and Therapeutics Committees in Eastern, Central and Greater Accra Regions.

Training of Institutional Contact Persons (ICPs) in the FDB Zones

The Unit in collaboration with the Zonal Offices successfully organised training programmes for ICPs in nine regions of the country. The workshop was organised to retrain old ICPs and also to train new ICPs that have not benefited from the training programmes organised by the FDB. A total of 149 healthcare professionals were trained in the various Zones. Below is the number of ICPs trained in each Zone;

1. Upper West/Upper East-25
2. Northern-42
3. Ashanti/Brong Ahafo-26
4. Volta/Eastern-26
5. Central/Western-30

Senior Managers of Public Health Programme (PHP) and Post National Immunization Day (NID) performance review meeting

The Unit made presentations during the two (2) meeting of senior managers of public health programmes (PHPs) on the need for inclusion of pharmacovigliance in PHPs.

The Unit facilitated a session on strengthening Adverse Event following Immunization (AEFI) during the post NID performance review meeting of regions and districts in Kumasi on June 16, 2009

Conferences and Meeting

The Unit was represented at the National Centers and International society of Pharmacovigilance meetings held in Morocco and France, respectively, in the year under review.

Safety Communications

During the year under review, the Unit circulated eight (8) Dear Healthcare Professional letters.

1. Decisions received from some regulatory authorities regarding safety and efficacy of OTC cold and cough medicines in children.

2. The use of Toremifene in patients at risk of QT-prolongation or other heart problems.
3. Black box warning and risk mitigation strategy for metoclopramide containing drugs
4. Suspension of marketing authorisation of Efalizumab (Raptiva) due to safety concerns.
5. Precautionary alert on the use of oral pain relief gels containing salicylates in children less than 16 years of age.
6. Communication about on-going safety review of Orlistat
7. Precautionary voluntary recall of Cevarix Vaccine batch AHPVA043BB in the United Kingdom by market authorisation holders; GlaxoSmithKline (GSK) following adverse events following immunization.
8. Amendment of the international package insert of Remicade (Infliximab) Injection by Schering-Plough (Pty) ltd; market authorization holders and manufacturers.

2.2 Drug Inspectorate Department

The Drug Inspectorate Department of the Food and Drugs Board is made up of the following operational units:

- Premises Inspection Unit
- Post-Market Surveillance Unit
- Industrial Support Service/Operational Research

The Department's main activities include the pre-licensing and post licensing inspections of pharmaceutical, herbal, cosmetic and household chemical substances manufacturing industries. The Department also conducts inspection of local and overseas drug manufacturing facilities to verify compliance to Good Manufacturing Practice (GMP).

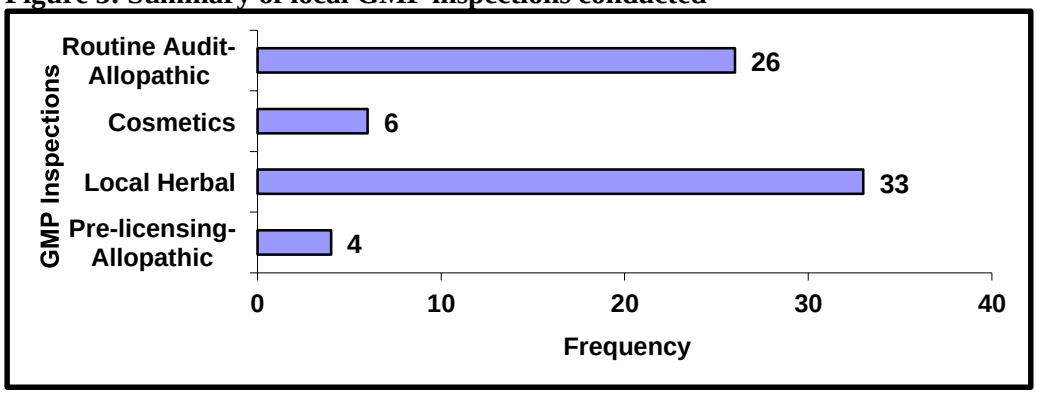
2.2.1 Drug Premises Inspection Unit

The principal functions of Drug Premises Inspection Unit are:

- To conduct routine, announced, unannounced Good Manufacturing Practice (GMP) audit inspections in all local licensed pharmaceutical manufacturing facilities for the production of allopathic and herbal drugs, cosmetics and household chemical substances.
- To conduct pre-licensing inspections for new applicants and evaluation of block plans of new manufacturing facilities.
- To conduct site verification inspections in foreign pharmaceutical manufacturing plants in line with GMP Audit inspections for pharmaceutical companies that carry out business in Ghana.
- To conduct industry production capacity monitoring and control of extemporaneous preparations.

In 2009, 4 local pharmaceutical companies, 8 herbal manufacturers and 0 cosmetics industries were inspected as part of product registration and pre-licensing of premises requirements. The Unit was able to conduct routine audit inspections in 57 manufacturing companies that were registered and generally, the findings of the inspections indicated improvement in Good Manufacturing Practice. Figure 3 shows the routine inspections conducted in local allopathic, herbal, and cosmetics manufacturing plants.

Figure 3: Summary of local GMP inspections conducted



Source: 2009 Drug Inspectorate activities

2.1.1.1 External GMP Audit Inspections

Overseas GMP audit inspections of Pharmaceutical Companies carrying out business in Ghana were carried out during the period under review. In all, 24 pharmaceutical manufacturing facilities were inspected, all were found to be GMP compliant.

2.2.2 Industrial Support Services Unit

The Unit supports the activities of the Premises Inspection Unit and the Post Market Surveillance Unit of the Drug Inspectorate Department. The Unit supports these Units by capturing and managing qualitative and quantitative data together with operational guidelines of the Department. The Unit also monitors medicine adverts and coordinate training programmes of the Department. Finally, the Unit gives technical support to the manufacturing sector in the form of training workshops.

During the year under review, the Unit conducted 3 research projects namely Quality of Anti-malarial Survey Assessment (QAMSA) project, Antibiotic Project (World Bank) and Roadmap Project. The QAMSA project mandated the recall ordered for noncompliant batches of some products. World Bank Antibiotic project is awaiting results from the laboratory. A roadmap set for compliance by manufacturers to GMP by a stipulated date after the Roadmap project. The Unit was able to received 8 data which were managed accordingly. The Unit also monitored 209 medicine adverts; 63 were approved, 142 deferred, 4 rejected and 7 are pending. Out of the 142 deferred, 98 were for corrections, 25 had no caution statements, 9 had incomplete documents, 4 mentioned scheduled, II diseases and 4 had expired product registration.

2.2.3 Drug Post Market Surveillance Unit

The Unit monitors registered drugs, cosmetics, household chemical and medical substances that have been given marketing authorisation or otherwise that are in distribution on the Ghanaian market and is of right quality, safe and efficacious. The Unit therefore undertakes the following activities:

- Inspection of storage facilities.

- General and targeted market surveillance (conduction of product quality monitoring).
- Collaboration with Pharmacy Council to monitor quality of products on the Ghanaian market.
- Supervision of safe disposal of expired, unwholesome and confiscated products.
- Destination inspection in liaison with the Import and Export Control Department.
- Undertake investigations into consumer and other complaints.
- Undertake random sample products for analysis.

Summary of activities conducted by the Unit during the year under review include:

- Investigated 5 consumer complaints on drug counterfeiting. The appropriate regulatory measures were initiated to forestall the situation.
- Supervised the destruction of unwholesome, expired and confiscated pharmaceutical products from 22 pharmaceutical companies and certificates of destruction were issued accordingly.
- Conducted quality monitoring on 29 products in Accra Metropolis aand its environment. 9 of the product monitoring is on-going.

2.2.3.1 Task Force Activities

During the year under review, a task force was formed to ensure Anti-counterfeiting activities and Assessment of registration status of herbal products dispensed at various herbal clinic. Table 7 shows summary of task force activities conducted in 2009.

Table 7: Summary of task force activities

Programme	Activity	Outcome	Remarks
Assessment of registration status of herbal products dispensed at various herbal clinics	12 herbal clinics visited in Accra- Tema Municipalities	A total of 115 herbal products found to be unregistered	FDB has initiated actions to bring them into compliance with the law.
Assessment of level of compliance to new antimalarial policy	Importers, manufacturers, private and public health institutions,	Plain atersunate, amodiaquine, chloroquine, halofantrine, dihydroartemesinin, arthemeter (finished products and raw materials) detained	Awaiting final decision by the FDB
Registration status of products sold in supermarkets	Warehouses of 4 supermarkets-Kwatsons, Koala, Forewin and Shoprite were visited	Some unregistered products were found in the warehouses and the culprits invited for discussion	Two companies have presented list of unregistered products. Another company has discontinued importation of unregistered products but officially unknown to the FDB. One Company is yet to present list of unregistered products for registration
Registration status of foreign herbal products	Tasly was assessed	Tasly was found to have some unregisterd medical devices	Tianshi, Meilun and Forever Living could not be visited due to absence of key personnel. Tasly has been asked to register the medical devices found at their premises
Anti-counterfeiting activities	Investigations into alleged counterfeits of Augmentin, Zinnat Xenical, Coartem were conducted	Arrest of people involved in the importation and distribution fake Augmentin, Zinnat and Coartem	Analysis revealed absence of active ingredients in these products. Appropriate fines were imposed on culprits. Xenical was found to be genuinie but a variation in packaging
Follow-up of non-compliant products detained at the port	Monitoring activities of products released under detention from the port done and products sent to the laboratory for analysis	Some awaiting lab analysis results, those that passed have been released. Some expired shampoos found were recalled and awaiting destruction	Some of the non-compliant products were sold without recourse to the Board.

Source: 2009 task force activities

2.3 Tobacco and Substance of Abuse Department

The Tobacco and Substance of Abuse Department has the mandate to control tobacco, licit narcotic drugs, psychotropic substances and chemical precursors in Ghana. The FDB regulates the importation and use of these substances by means of a permit system and other regulatory functions. The importing companies have to furnish the FDB with advice of receipt, annual returns, and the requisitions for the ensuing year. The FDB also receives multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The FDB also sends quarterly and annual returns on the use and importation of narcotics and psychotropic substances to the International Narcotics Control Board (INCB) in Vienna.

In 2009, the FDB vetted and issued 62 import permits for controlled substances, which were monitored. 60 advice of receipt were received. 57 returns on utilised controlled substances monitored. 23 export authorisations endorsed and confirmed. Export authorisation was received before consignments reached the country.

3 FOOD DIVISION

The Food Division contributes to the achievement of the goals of the Food and Drugs Board for safeguarding public health by ensuring that all food products on the market meet appropriate standards of safety and quality through pre-marketing assessment of food safety and quality. This is achieved by evaluating all samples submitted in the registration process, premises inspection, and meeting labelling requirements.

The Food Division is also mandated to undertake inspection of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify conformance to Good Manufacturing Practices. In addition, the Division ensures that all imported and locally produced food products are of good quality and wholesome.

The activities of the Food Division are carried out by Food Safety and Nutrition Department, Food Inspectorate Department and Animal Products and Biosafety Department and these are supported by eight (8) operational units.

3.1 Food Safety and Nutrition Department

The Food Safety and Nutrition Department is made up of the following operational Units:

- Food Evaluation and Registration Unit
- Food Safety and Management Unit

3.1.1 Food Evaluation and Registration Unit

The principal functions of the Unit include:

- Vetting of product applications and samples for evaluation.
- Evaluation of food products.
- Registration of food products.
- Review of labelling and promotional materials.
- Processing of permits.
- Shelf life monitoring of food products.
- The Client Services support.

In 2009, a total number of 865 applications were considered for registration. Out of this number, 325 representing 38% were locally manufactured whilst 540 representing 62% were imported (foreign). Table 6 gives the summary of food products submitted and registered by the Unit.

Table 8: Summary of food products submitted and registered

Product Category	Imported (Foreign)	Registered (Foreign)	Locally Manufactured	Registered (Locally)
Drinks	212	116	78	64
Bakery Products	90	28	14	11
Fats and Oils and Emulsion	60	44	2	2
Condiments and Spices	2	5	4	9
Soups and Sauces	1	1	6	0
Confectionery	28	12	7	3
Packaged Water	0	0	170	129
Diary and Diary Products	15	8	11	12
Sugar and Sugar Products	5	6	0	4
Additives	8	12	1	2
Roots and Tubers	1	4	1	3
Fruits	4	0	0	1
Cereals	77	43	20	3
Vegetables	20	11	11	10
Animal Feed	4	2	0	0
Fish/Fish Product	10	11	0	0
Meat and Meat Products	3	1	0	2
Total	**540**	**304**	**325**	**255**

Source: 2009 Food Registration Activities

During the year under review, 104 products were deferred for the following reasons:

- Incomplete address of manufacture/agent
- Absence of name & address of Manufacturer/agent
- No Country of origin
- No date of manufacture/ minimum durability
- No batch number
- Misleading labelling/claims
- No net weight
- Ingredients not specified
- Failed laboratory results

- Unsubstantiated claims on labels
- Labelling ink not indelible
- Inadequate Certificates of Analyses.

3.1.1.1 *Codex* Commission

During the second quarter, officers of the Unit had the opportunity to observe proceedings at the 18th Session of the FAO/WHO Coordinating Committee for Africa which was held at the Accra International Conference Centre.

3.1.1.2 Group Registration (Melcom Ghana Ltd)

An evaluation was carried out from Melcom Ghana Limited under the Group Registration exercise at the premises of the company from the 27th to 29th April 2009.

3.1.1.3 Training On HACCP and Audit of HACCP Systems

At the latter part of the second quarter, the Head of Unit attended a training programme on HACCP and Audit of HACCP Systems in Porto, Portugal.

3.1.1.4 Training On Attitudinal Development In Competitive Market

A member of staff attended a training program on attitudinal development in competitive market environment at the Mensvic Hotel, Accra on the 24th and 25th September, 2009.

3.1.1.5 Site Verification

Two members of the Unit conducted an audit at New Age Beverages Company Limited in Nigeria from 25th November to 28th November 2009. This was in response to an application for the registration of their products, So Good Soy Milk (Natural Strawberry, Vanilla Banana and Chocolate).

3.1.2 Food Safety Management Unit

The Food Safety Management Unit (FSMU) is one of the Units under the Food Safety and Nutrition Department. Since its inception in March 2004, it has been actively involved in the execution of the following functions:

- Organisation of In-House training for staff.
- Inspection of Food Safety Management Systems in the Food Service Industry.
- Assisting the Food Service Industry to implement Food Safety Management Systems.
- Public Education on Food safety Issues.
- Cooperative programs with state and local governments.
- Regulatory and research programs to address health risks associated with food borne chemical and biological contamination.
- International Food Standard and Safety harmonisation efforts.

In 2009, the Unit conducted Food Audit in a number of restaurants and hotels in Accra – Tema Metropolis. Out of 428 facilities audited, 127 were recommended, 166 were not recommended, 135 did not have a functional kitchen, and one restaurant facility refused inspection. In the Central region, 67 facilities were audited, 22 facilities were recommended, 16 facilities were not recommended, 29 facilities did not have a functional kitchen.

On Food Hygiene permits, 206 facilities were issued with Food Hygiene Permits. 585 Street Food Vendors were also trained, in the Ashiaman Municipality and the Tema Metropolis.

3.1.2.1 Courses/Seminars/ Conferences Attended

As part of building capacity, some staff members of the Unit attended series of seminars and conferences as follows:

- Two members of the Unit attended the 18th Session of the FAO/WHO Coordinating Committee for Africa and FAO Workshop on Mycotoxins at the Accra international Conference Center.

- Four members of the Unit attended the 3rd GO-GLOBAL Conference at the Alisa Hotel in Accra.
- The Unit Head attended the 37th Session of the Codex Committee of Food Labelling in Calgary, Canada.
- A staff attended the 3rd GO-GLOBAL Planning Committee and the 2nd Central Planning Committee of the 7th National Food Safety Week Celebration Meetings at the T.C. Corquaye Conference Room.
- The Unit Head attend a Seminar on "Safe Use of Waste Water in Agriculture in Ghana" in Accra.

3.2 Food Inspectorate Department

The Food Inspectorate Department is one of the three Departments making up the Food Division of the FDB. The responsibilities of the Department are performed by three units; namely Food Post-Market Surveillance Unit (FPMSU), Food Premises Inspection Unit (FPIU) and Industrial Support Services Unit (ISSU).

3.2.1 Food Post-Market Surveillance Unit

The major functions of the Unit are:

- Inspection of dry food storage facilities (Food Warehouse) to ensure their compliance to Good Warehouse Practice (GWP) as a guarantee for the safe storage of food products.
- Investigate into consumer complaints and related issues.
- Monitoring of practices employed in the retail of pre-packaged food to safeguard public health and safety.
- Vetting and approval of food product advertisement applications.
- Training of stakeholders in relevant areas of the Food Law.
- Enforce Compliance to Breast Feeding Code.

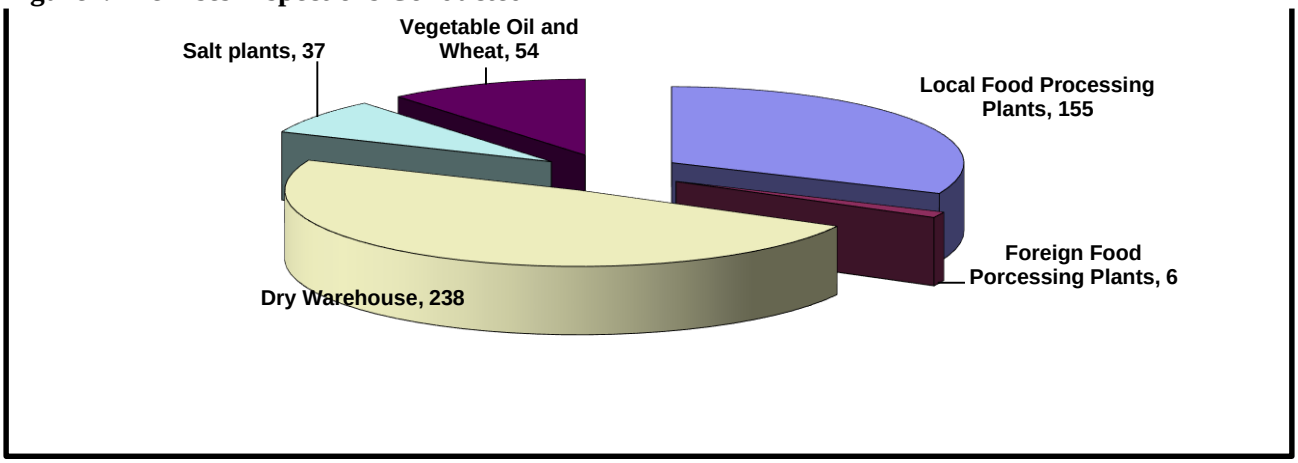
3.2.2 Food Premises Inspection Unit

The Food Premises Inspection Unit (FPIU) carries out the following functions to support the activities of the Food Division:

- Inspection of food processing facilities to assess compliance to current codes of GMP, Good Hygiene Practice (GHP), and other food safety management systems as a guarantee for the production of safe and quality food products.
- Conduct investigation into consumer complaints.

During the year under review, 626 types of inspections were conducted covering Local Food Processing Plants, Foreign Food processing Plants, Dry Warehouse, Salt Plants, vegetable Oil and Wheat Flour and Supermarkets and retail outlets. Figure 7 indicates the summary of frequency of inspections conducted in 2009 at the various food plants.

Figure4: Premises Inspections Conducted



Source: 2009 Food Premises Inspection Activities

Based on the outcome of the inspections and other non-compliances noted, the Unit included a training activity in its programme. In consequence, the Unit organised training in GMP and Food Safety management System based on the Principles of Hazard Analysis and Critical Control Point (HACCP) for Quality Assurance Officers of local Alcoholic Beverage Producing Companies.

In the course of 2009, the Department embarked on special swoops on the distribution and sale of fake/imitated food products. Target items included, processed canned fish, food seasoning and alcoholic beverages. Food items worth more than fifty thousand Ghana Cedis (GH¢50,000.00) were seized and destroyed.

3.2.3 Industrial Support Services Unit

The Unit provides the following functions to support the Food Division:

- Provision of technical support to the food industry through training and implementation of food safety and quality management systems.
- Control of export of palm oil to the European Union.
- Implementation of GAIN project on fortification of wheat flour and vegetable oil with micronutrients.
- Implementation of Universal Salt Iodation (USI) programme

3.2.3.1 Food Industry Audit and Workshops/Seminars

To upgrade the knowledge of small scale and medium enterprises and other stakeholders, the Unit organised training in Food Safety and Quality Management Systems based on the Principles of HACCP for producers of the following categories of food products;

- Flavoured (Synthetic) Drink
- Drinking Youghort and Cocoa Beverage Drink
- Sachet Water
- Alcoholic Beverage (Strong Liquor)

3.2.3.2 Regulation of the Safety and Quality of Palm Oil

The Unit regulate the safety and quality of palm oils produced in the major producing areas in Ghana, adulterated of palm oil with Sudan dyes this is to facilitate export and ensure consumer protection, in 2009, the Unit received 134 applications and all were issued with Export Permit. For the first time of palm oil regulation, no aleart/rejection of Palm oil were received from the European Union. One significant observation made was that majority of the palm oil exporters in Ghana are small scale.

3.2.3.3 Management of Food Alert

During the year under review, 16 rapid alert systems for food and feed were received and only 11 were investigated.

3.2.3.4 Universal Salt Iodation Programme (USI)

The objective of the programme is to achieve 90% household consumption of iodated salt in Ghana. During the period under reivew, the Unit made 82 visits to police/CEPS barriers

and conducted 5 market surveys. 42 Salt Movement permits were issued in 2009 to transport Iodated salt.

3.2.3.5 National Food Fortification Alliance (NFFA)

The Ghana National Fortification Programme aims at reducing the prevalence of micronutrient deficiencies among vulnerable and at risk populations. The principal activity is to monitor and sample producers of wheat flour and vegetable oil for quantitative laboratory analysis of vitamin A and iron. In 2009, 2 market surveys were carried out in Accra and Tema and samples analysed. The results indicated acceptable levels of vitamin A and iron in the fortified foods.

3.2.3.6 Validation and Commissioning of HACCP Systems

The objective of these exercises is to assist medium and large scale enterprises validate their HACCP systems. Installation of HACCP system in food plants at Accra Brewery Limited (ABL) and Voltic Ghana Ltd were completed. A HACCP certificate was issued to the company and the HACCP system officially commissioned.

3.2.3.7 Supervision on Destructions Operations

In 2009, 37 applications were recieved on wholesome food and food related products for dustruction and supervision. 27 were supervised and the remaining 10 were pending.

3.3 Animal Products and Biosafety Department (APBD)

The Department was created in August 2007 to ensure the safety of foods of animal origin (meat, poultry, fish, Milk and Honey), animal feed and regulate genetically modified (GM) foods/feeds imported into Ghana. The APBD comprises three units;

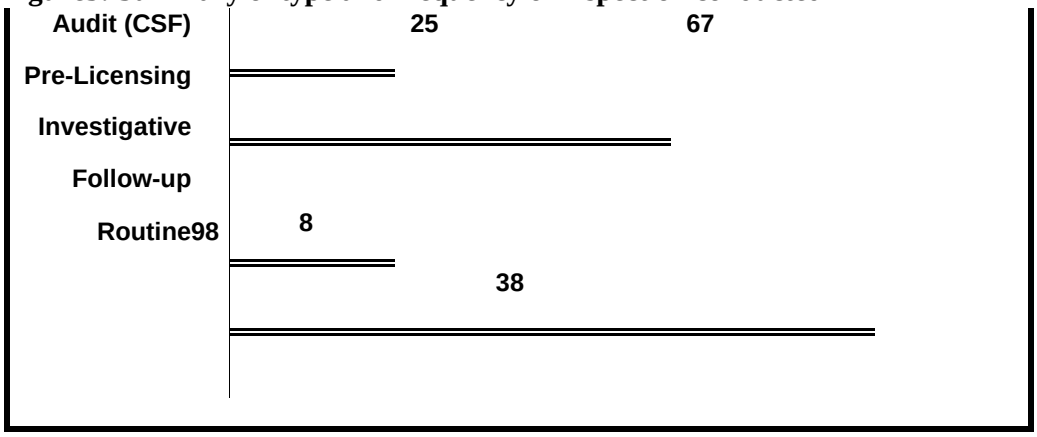
- Animal Products Unit (APU)
- Feed Safety Unit (FSU)
- Biosafety Unit (BU)

The functions of the Department include:

- Inspection of Cold Sstorage facilities to ensure Good Cold Storage Practices (GCSPs).
- Inspection of Feed mills to ensure Good Manufacturing Practices (GMPs).
- Technical Evaluation of Genetically Modified (GM) Foods/Feed
- Organisation of training workshops on GCPs and GMPs for meat and feed industries.
- Consumer education on safety of products of animal origin.

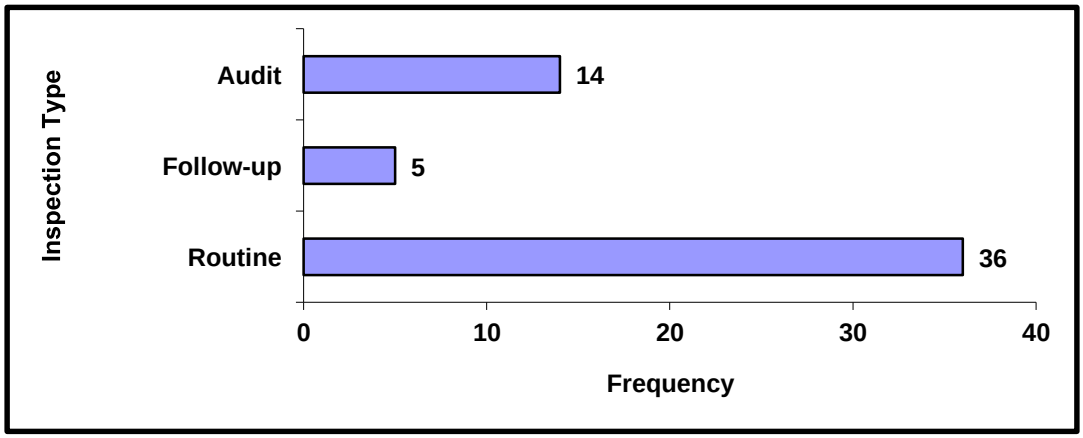
In 2009, figure 8 and figure 9 show the types of inspections the Department conducted, respectively.

Figure5: Summary of type and frequency of inspection conducted



Source: 2009 Inspections of Animal and Biosafety Department.

Figure6: Summary of Feed Mills Premises Inspections conducted



Source: 2009 Inspections of Animal and Biosafety Department.

The main non-conformances observed during these inspections included:

- Non- calibration of weighing scales
- Lack of pest control programmes
- Lack of proper documentation
- Poorly maintained ancillary facilities

Recommendations were given to companies to address all the non compliances observed.

Table 9: Number of Vessels Inspected per Local Consignee

Local Company	Number of Vessels
Holly fax	3
Laud of Milk	6
Ocean Fare Limited/ Inter Oasis	4
We 2 Sea Foods	5
Adom Mbroso	4
Unique Concerns	4
Servistar/ Minwax Limited	3
Reliance Commodities	3
Cocas Impex	2
Amisachi	2
Stallion Industries	1
Krobeason	1
Double Crown Investment Limited	1

Dolphin Frozen Foods Limited	2
Fbilo God dey	1
CCTC	1
Movelle Company Limited	1
Crystal Frozen Sea Foods**	1
ETS Harounda Dia**	1
Total	**46**

** Vessels on transit to neighbouring countries-
Source: 2009 Inspections of Animal and Biosafety Department

All the vessels inspected adhered to Good Cold Storage Practices and were cleared for their cargo to be released.

The table below shows the number of facilities inspected in the regions.

Table 10 -Regional Inspections

Regions	Cold Storage Facilities	Slaughter Slabs and Abattoirs
Ashanti	9	3
Brong-Ahafo	6	3
Central	5	2
Western	3	3
Total	**23**	**11**

Source: 2009 Regional Inspections of Animal and Biosafety Department

The main non-compliances observed during these regional inspections included the following:

1. Lack of medical certification of staff
2. Absence of evidence of pest control program
3. Poor record keeping

3.2.1 Dossier Evaluation on Animal Feed Registration

Two (2) applications received from prospective importers of feed additives had their dossiers evaluated to determine the level of conformity of their products to safety and quality requirements. This was done as a pre- requisite for the registration of these products.

3.2.2 Visited by a delegation from the International Feed Industry Federation (IFIF)

The department hosted a three-member delegation from the International Feed Industry Federation within the period. The following were the programs embarked upon:

1. Meeting with Stakeholders in the feed industry including the Ghana Feedmillers Association, Ghana National Association of Poultry Farmers and Regulatory Bodies.

2. Visit to some selected Research Laboratories (National Feed Laboratory ;Veterinary Services Laboratory; Animal Science Laboratory-University of Ghana, Legon)

3. Familiarization tour to some Feedmills in the Accra and Tema Metropolis. This included Ghana Protein, Ghana Association of Poultry Farmers, Hapilla Feedmill and Ghana Agro-Food Company

4. Meeting with the Academia at the University of Ghana, Legon. During this meeting, the need for research into improved feed manufacturing was highlighted.

5. Currently, the Department is conducting inspections of feedmill and fishmeal facilities in the Ashanti and Brong Ahafo regions to ensure that their operations adhere to Good Manufacturing Practices (GMFPs).

3.3.1 Biosafety Unit

Two members of staff of the Department attended the second GenØk sub-regional Biosafety course- Hazard identification and Risk assessment in Norway. Since their return a series of in-house presentations on the knowledge acquired at the program has been going on.

In 2009, an in-house training programme was organized for 42 staff members of the Food Division with the aim of deepening awareness on Biosafety within the Division, which covered major topics in Genetically Modified Foods. In addition to the in-house training programmes, other staff members like National Service personnel and attachment staff also benefited from the 7 topics treated by the Unit.

3.3.1.1 Articles for Public Education

In 2009, twelve (12) thematic articles were submitted for publication in the various print media. The articles covered topical issues on Biosafety, Feed Safety, Egg Safety, Honey Safety and Good Meat Handling and Processing Practices.

4 Import and Export Control Department

The Import and Export Control Department (IECD) is mandated to regulate the importation and exportation of food, drugs, cosmetics, household chemical substances, and medical devices in accordance with the PNDC Law 305B. The activities of the department are concentrated at the various entry routes to the Country. The Department started operation in September 2007.

The departments' activity covers the Tema Port, Kotoka International Airport (KIA) and the Issuance of electronic permits by GCNet System. The operational areas include various freight stations and carrier terminals at the KIA as well as container terminals, freight stations, sheds and wharf sites at the Tema Port. The details are listed below:

1. Electronic Permit System-GCNET

Tema

2. Main Port (Wharf Sites and Sheds)
3. Tema Container Terminal (TCT)
4. Maersk Container Terminal (MCT)
5. Africa Coastal Services (ACS) Terminal
6. Tema Bonded Terminal (TBT)
7. Golden Jubilee Terminal (GJT)
8. Container Freight Station (SDV, DHL,CONSHIP, Maersk)
9. SCAN

KIA Office

1. DHL warehouse
2. Courier dome
3. Aviance warehouse

The main functions of the Department are:

- Receiving and processing import permits electronically.
- Inspection of regulated products at the ports and duty posts
- Identification and streamlining of all permits and registration issues before regulated products are released to importers.

- Verification of international documents accompanying regulated products imports and exports.
- Compilation of Data on regulated products imports and export at the various entry points.
- Gather intelligence on smugglers and investigate sources of fake regulated products.
- Education of stakeholders (importers and exporters) of regulated products on Board's requirements for importation and exportation of the said products.

4.1 Issuance of Permits

Prior to the establishment of the Department, the FDB had been issuing manual permits for the clearance of products it regulates. The FDB officially commenced the issuance of electronic permits for clearance via the Ghana Community Network Services, GCNet, on the 22nd January, 2008. This system became fully operational in June, 2008.

4.2 Inspections/Clearances

Inspections/clearances of imported food and drugs products carried out by the Department, at both Tema Port and KIA during the year is tabulated below:

Table 11: Clearances/Inspections via Electronic Permit System

Month	Clearances/Inspections Made						
	Food	Drugs	Household chemical substances	Cosmetics	Medical Device	Tobacco	Total
January	258	116	17	22	14	1	**428**
February	357	156	32	30	12	2	**589**
March	273	139	10	25	5	-	**452**
April	229	119	28	15	27	1	**419**
May	306	124	24	13	31	2	**500**
June	272	115	31	24	42	3	**487**
July	322	102	40	49	10	2	**527**
August	356	116	51	50	14	2	**589**
September	367	129	49	35	8	1	**588**
October	547	134	51	43	15	3	**793**
November	432	122	53	41	13	2	**663**
December	664	181	58	45	32	0	**980**

Total	**4,383**	**1,553**	**444**	**392**	**223**	**19**	**7,015**

Source: 2009 Import and Export Control Activities

4.3 KIA Unit Operations

A total of 1,886 inspections were conducted at the KIA for the period under review. Samples or products brought into the country via courier were also conducted within the period under review. The monthly breakdown of the inspections is as shown in the table 12.

Table 12: Clearances/Inspections carried out during the year at KIA

MONTH	NUMBER OF INSPECTIONS	INSPECTIONS AT COURIER
January	151	17
February	152	17
March	159	16
April	157	28
May	155	33
June	166	25
July	152	28
August	102	32
September	105	45
October	137	40
November	138	39
December	312	6
Total	**1886**	**326**

Source: 2009 KIA Unit Operations

4.4 Cargo Tracking

The Pre-inspection Monitoring Unit of the Department continues to track the cargo manifests of all ships that dock at the Tema harbour as well as Final Classification and Valuation Report (FCVR) of all imports in its bid to prevent freight forwarders/importers from circumventing the FDB's clearance procedure. The Department also visits Agencies that have maneuvered to clear products that the FDB should have inspected and such culprits brought to book. This has contributed to the increased revenue observed over the period.

4.5 Patrols at the Terminals

The Tema Office of the Department patrols the various container terminals daily to fish out freight forwarders/importers that bypass the FDB to clear products that are under our jurisdiction.

4.6 Rejection of imported rice on Board MV Stefanis

Within the last quarter of the year, the Food and Drugs Board through the efforts of the Department rejected bulk rice that was imported into the country. The said rice was observed to be weevil infested.

4.7 Bulk Frozen Fish, Meat, Rice and Sugar Inspections

The Department has gained grounds in the inspection of frozen fish and meat products that arrive in reefer vessels. Inspections on board the vessels are carried out by expert teams involving the IECD and the Animal products and Biosafety Department. Efforts are being made at completely roping in frozen fish and meat products that arrive in reefer containers.

5 Quality Control Laboratory

The Quality Control Laboratory provides laboratory services in the form of quality evaluation of Food, Drugs, Cosmetics and Chemical Substances. The Laboratory plays the role of determining the quality of these products, thereby enabling the Board to take regulatory decisions. The laboratory performs chemical, physical and microbial analysis of chemical and herbal drugs. The quality parameters employed are as established in standard compendia indicated in schedule IV of the Food and Drugs Law (PNDCL 305B). It also supports both internal and external clients by providing reliable analytical and advisory services. The functions of the Quality Control laboratory are carried out by three main Units namely:

- Physicochemical Unit
- Microbiological Unit and
- Medical Devices Unit

5.1 Physicochemical Unit

The Physicochemical Unit undertakes quality investigation by considering physical and chemical properties and behaviours of products. The products the Unit handles are mainly food and food related products, drugs (allopathic, herbal and veterinary), cosmetics and household chemical substances.

The Unit accepts samples from Drug Registration Department, Food Safety and Nutrition Department, Inspectorate Departments, Post-Market Surveillance Units, Port Offices and Zonal Offices. The Unit also receives samples from external organisations for analysis, such as Criminal Investigation Department (CID) of the Ghana Police Service, Custom Excise and Preventive Service (CEPS), Central Medical Stores (CMS) of Ghana Health Services, and the Pharmacy Board of Sierra Leone.

5.2 Microbiology Unit

The Microbiological Unit started operating in June 2004. The Unit undertakes microbiological testing of samples including food and food products, water, nonalcoholic beverages, drugs, cosmetics, and herbal preparations.

The analytical tests include the determination of aerobic plate count, yeast, mould count, and coliform count. The determination of faecal streptococcus, pseudomonas as well as the detection and enumeration of pathogenic and toxigenic microbes such as Salmonella, Staphylococcus aureus, Escherichia coli, Clostridium perfringens, and Bacillus cereus in food, water, drug and cosmetic samples are some of the functions of the Unit.

5.3 Medical Devices Unit

The Medical Devices Unit of the Quality Control Laboratory started operation in June 2004 following successful installation of the following equipment from Valendor, Sweden:

- Four Station Air Inflation Tester
- Electric Hole Tester
- Water Leakage Tester
- Tensile Testing Machine and Cutting Press
- Water Vacuum Bowl and Vacuum Bowl for package seal
- Aging Oven
- Mandrel and Digital Gauge and others

5.4 Extent of Performance and Achievements in Product Testing

The Department received a total of two thousand seven hundred and sixty seven (2767) samples for quality evaluation for the year under review. This represents a decrease of one hundred and thirteen (113), (3.92%) in comparison with the number of samples received in the previous year 2008 (2879). These were made up of allopathic drugs (41.6%), cosmetics and household chemical substances (7.5%), food (29.2%), herbal drugs (12.6%), medical devices (7.2%) and veterinary drugs (1.9%). Table 10 gives the summary of product categories received for the various analytical tests.

Table 13: Summary of product categories received and analyzed

Sample Category	Received	Analysed	Not Analysed	Passed	Failed
Allopathic Drugs	1147	979	168	909	70
Herbal Drugs	349	267	82	204	63
Veterinary Drugs	52	52	-	52	-
Food	813	733	80	646	87
Cosmetics & Household Chemical Substance	206	206	-	188	18
Medical Devices	200	122	78	118	4
Total	**2767**	**2359**	**408**	**2117**	**242**

Source: 2009 Laboratory Analysis

5.5 Projects Executed

In 2009, the Quality Control Laboratory undertook three (3) projects. The details are given below.

5.5.1 Food and Drugs Board/UNICEF Project

The project aims at the quality monitoring of Antimalarial preparations in Northern Ghana. The project was sponsored by UNICEF. In 2009, the three (3) Northern Regions were surveyed and samples taken for laboratory analysis. The project had been completed and the final report submitted to UNICEF.

5.5.2 Food and Drugs Board/USD-DQI Antimalarial Project

Five Hundred (500) samples from five (5) sentinel sites in the country were analysed using Minilabs at the sites. Full monograph analysis was carried out for sixty-two (62) samples at the Food and Drugs Board (FDB) laboratory in Accra. The complete report has been forwarded to strategic management for action. The final report of the fifty percent (50%) of the samples from the QAMSA study in 2008 which were sent to the World Health Organisation (WHO) Centre for Quality Assurance of Medicine (CENQAM) was received

in the year under review. The necessary regulatory actions were taken which lead to the recall of some batches of twenty two (22) Antimalarial preparations from the Ghanaian Market.

5.5.3 Food and Drugs Board/World Bank Project

The Food and Drugs Board with the support from the World Bank sampled three hundred and fifty (350) preparations of Amoxicillin, Co-Amoxiclav and Ciprofloxacin for quality evaluation as part of its Post Market Surveillance (PMS) activities. Analysis of these samples and the final report will be completed by the end of February 2010

6. Zonal Operations

The FDB operates Regional and Zonal Offices to fulfil its mandate of regulating food, drugs, cosmetics, household chemical substances and medical devices to ensure its quality,

safety and efficacy. In 2009, the FDB operated 3 Regional Offices and 3 Zonal Offices that are indicated below.

- Kumasi Regional Office, responsible for Ashanti region.
- Tamale Regional Office, responsible for Northern region.
- Sunyani Regional Office, responsible for Brong Ahafo region.
- Bolgatanga Zonal Office, responsible for Upper East and Upper West regions.
- Takoradi Zonal Office, responsible for Central and Western Regions.
- Ho Zonal Office, responsible for Eastern and Volta regions.

Generally, the activities of the Zonal/Regional Offices which are mainly operational cover the following areas:

- Conduct premises inspections.
- Carry out post-market surveillance exercise.
- Conduct advert monitoring
- Embark on consumer awareness programmes.
- Organised meeting for stakeholders.
- Organise sensitization programmes, seminars, workshops, and training for all stakeholders in the food and drug industry.
- Investigate consumer complaint protocols to deal with consumer issues.
- Sale and assisting manufacturers, producers and importers in the registration of the regulated products.

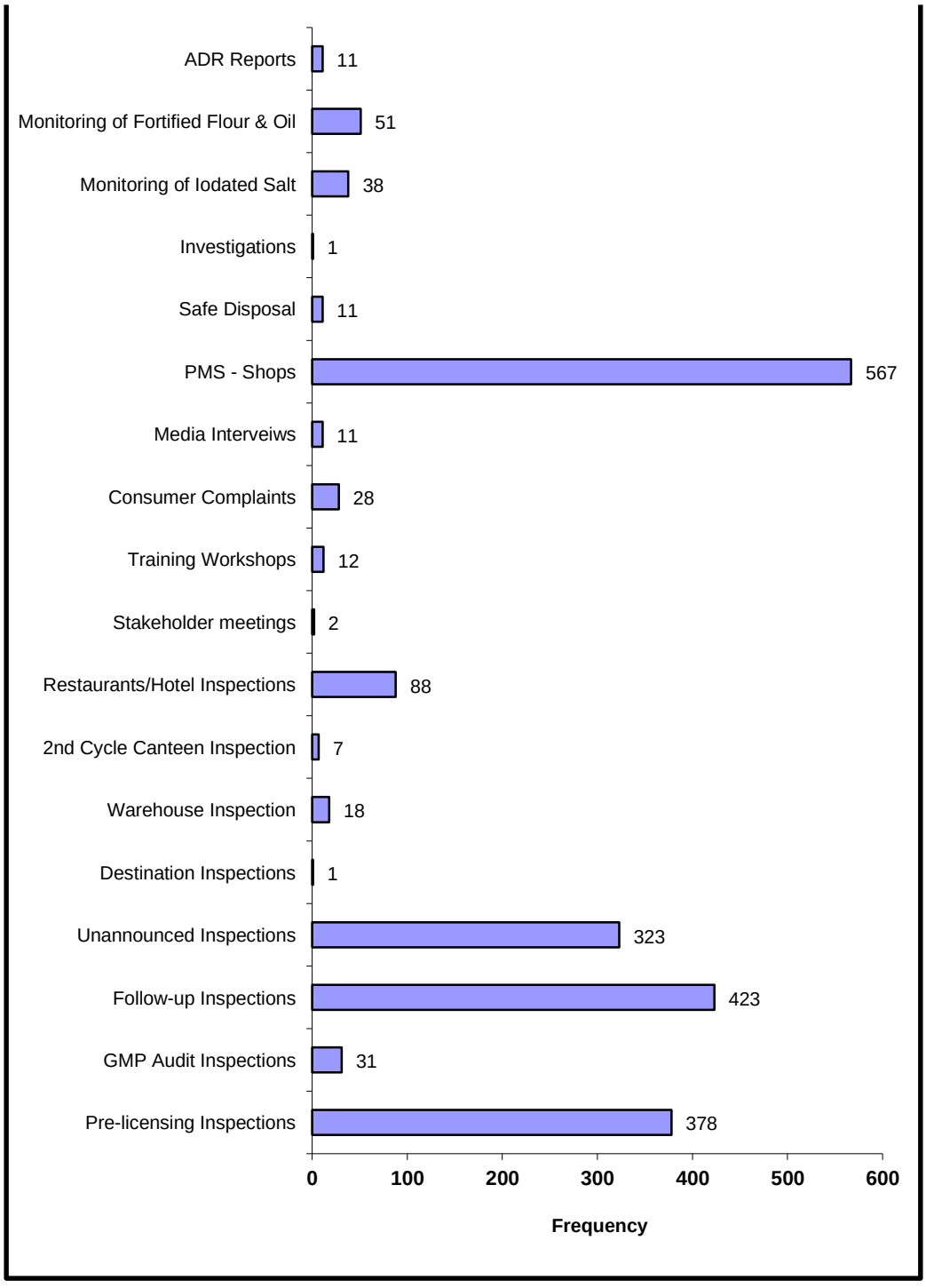
The internally generated funds of the Zonal Offices come from the activities of sale of registration forms, advertisement forms, advertising right fees, destination inspection fees, destruction fees, and product registration fees.

6.1 Extent of Performance and Achievements of Zonal/Regional Operations

Most of the activities during the year under review centred on pre-licensing inspection of small-scale food producers. The post-market surveillance function was to ensure that expired drugs and food products, unregistered drugs and food, as well as unwholesome food, which were sold to innocent consumers, were taken off from the shops. Meetings,

seminars/workshops with stakeholders and media interviews and programmes were some of the prominent activities. Figure 12 shows the summary of activities performed by the Zonal/Regional Offices.

Figure 7: Extent of Performance of Zonal/Regional Operations.



Source: 2009 Zonal/Regional Operations

7. Administration

The Administration Department of the Food and Drugs Board supports the services of the various technical Departments of the FDB. The Department provides services in the areas of general management and administration (which includes administrative support to all

the divisions and departments, transport management, estates management and security), human resource management and procurement management.

7.1 General Administration Unit

The general administration functions cover all the secretarial duties, transport and estate management of the FDB.

7.1.1 Transport

The activities for the period were as follows:

- Implementation of transport Management System.
- Organization of training for drivers.
- Improvement on the use of forms and logbooks by vehicles operators and users for better data collection.

The implementation of the transport management System has ensured that the vehicles were well-maintained and were under control after close of work. At the same time record keeping and data collection has improved through the use of logbooks.
There was a reduction in the cases of driver indiscipline, hence no major accident occurred in the course of the year.

7.1.2 Estates

Within the year under review, there was a lot of activity, especially in the maintenance of the estates due to the increasing numbers of staff, both permanent and temporary, and the influx of huge numbers of National Service persons.

- The renovation of the zonal residential bungalow in Sunyani has been completed.
- General repairs and maintenance of the buildings, plant and equipment saw significant improvement throughout all the offices of the Food and Drugs Board
- The new building of Food and Drugs Board located behind the Nurses' hostel is has been suspended and the contract for its completion is yet to be re-awarded.
- A new pump has been fixed to the underground watertank.

7.2 Human Resource Unit

During the year under review, the FDB got financial clearance from the Ministry of Finance and Economic Planning to recruit personnel to fill existing vacancies. Sixty-four (64) establishments were given, which comprises fifty (50) Regulatory Officers, four (4) Administrative Officers, four (4) Secretaries, Four (4) Electrical Technician and two (2) Drivers. The FDB has fifty-eight (58) temporary staff and 72 national Services personnel supporting the operational functions across the FDB. Table 14 below shows the total number of permanent staff of the FDB in 2009. In 2009, 4 permanent staff and 7 temporary staff resignations were recorded.

Table 14: Summary of permanent staff

Office Type	Total Staff Strength
Head Office	213
Kumasi Regional	19
Tamale Regional	7
Sunyani Regional	9
Ho Zonal Office	13
Bolgatanga Zonal Office	7
Takoradi Regional Office	13
Total	**272**

Source: 2009 Human Resource Data

To ensure human resource capacity building, two (2) administration staff were trained on Management Principles at GIMPA. Various employees in various Departments attended varied categories of training programmes, workshops, seminars and conferences. The role of Human Resource has slightly improved but can be further improved significantly.

7.3 Procurement Unit

The Procurement Unit was established to ensure that internationally accepted standard procedures are followed in all FDB procurement activities. This was done within the context of a national procurement code, Public Procurement Act 663 enacted in 2003.

The main objective of the FDB procurement process was to establish a system of procurement that is transparent, competitive and ensure accountability and fairness. The Unit handles all procurement issues of the FDB in accordance with the procurement law. This is done through International Competitive Tendering (ICT) and National Competitive Bidding (NCB), respectively. In 2009, nine (9) International Competitive Bidding (ICB),

three (3) National Competitive Tendering (ICT), one (1) Restrictive Tendering (RT) and Six (6) Shopping activities respectively, were carried out. These covered the needs budget of the FDB.

7.4 Projects, Research and Management Information system (PRMIS) Unit

The Projects, Research and Management Information System (PRMIS) Unit plays the role of a co-ordinating centre for projects and research activities within the FDB, and to oversee the development, administration and maintenance of the Board's Management Information Systems (MIS). The Unit is also responsible for compiling and producing the final draft of annual reports and programmes, as well as research reports from all Departments and Units of the Board. The Unit also advises management in all matters related to Information and Communication Technology.

As part of programmes to support regulations in 2009, the following activities were achieved.

E-mail System and Web Hosting

The FDB continued hosting its website and deployed the corporate e-mail system. The local area networks were enhanced to enable management of groups, network resources and users.

Shared Information Functions

The is internet facility installed at the Head Office, the Quality Control Laboratory and all the Zonal Offices except the newly created boarder posts continued to receive improved service. The internet service facility was installed to enhance information search and downloads of relevant documents on food and drugs regulation. The Unit maintained and support the following applications and database at the various Departments.

Installation of Electronic Permit System under the Ghana TradeNet System

The electronic permit software was changed from the client/server environment to a browser-based to ease its usage. The connectivity at Takoradi Office and Elubo office, respectively will be undertaken in 2010.

Submission of Reports

In 2009, copies of project/research proposals and completed project/research reports were not submitted to update project/research database of the FDB. The Unit has not received such reports since 2005 even though a number of projects/research functions are going on.

8.0 Support Units under the Chief Executive Office

The following Units, which report directly to the Chief Executive (CE) of the FDB, also perform duties that significantly support the functional activities of the FDB. They are Legal Audit and Communication Units.

8.1 Communications Unit

The Unit serves as an interface between the Board and its stakeholders, which includes the media, the business community, industry and consumers. The Unit arranges for foreign travels, various media programmes particularly with respect to consumer education, and media coverage of the Board's activities. The Unit also ensures the publication of health alerts and press releases for the information of the public and the international community at large. Assisting in the organisation of swoops with the police and the media is another function of the unit.

During the year under review, the activities performed under the Communication Unit are as shown in the table below.

Table 15: Activities conducted by the Unit

Area of Activity	Frequency	%
Media Coverage	10	6.8
Media Interviews	25	16.9
Press Releases, Disclaimers, Notices	13	8.9

Visas Acquired (India, USA, Canada, South Africa, China, Netherlands, Germany, Morocco, Brazil	35	23.6
Tickets Purchased (India, USA, Canada, Switzerland, Lagos, Italy, Hungary, Singapore, Kenya	58	39.2
Travel Insurance	7	4.7
Total	**148**	**100**

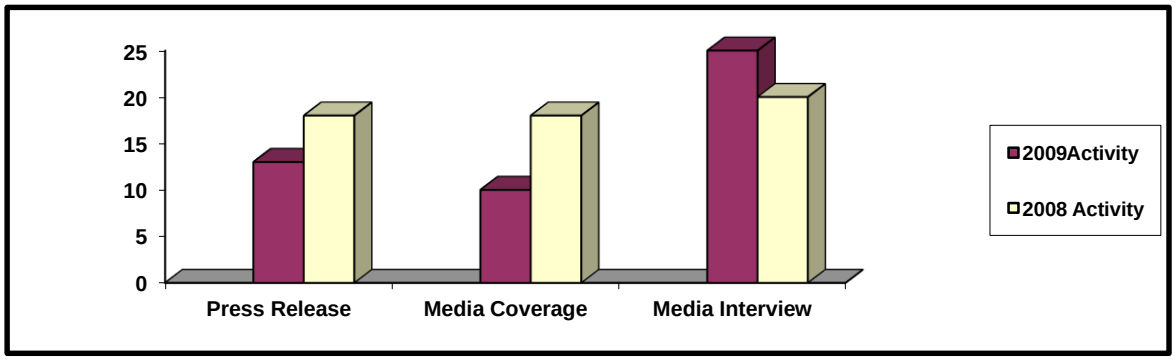
Source: 2009 Communication Activities

8.1.1 Collaborative Functions with other Departments.

The activities organised during the year, which the Unit played a key role for their successes were;

1. The 3rd GO-GLOBAL conference was organised on the theme; "*EMERGING FOOD SAFETY RISKS: CHALLENGES TO INTERNATIONAL TRADE*".
2. Destruction of some seized expired products at Mallam dumping site.
3. Media visit to some herbal facilities in Tema and Accra
4. Media coverage of an imposter as an FDB staff at a chop bar at Circle
5. The Food and Drugs Board in collaboration with the United States for International Development (USAID) and US Pharmacopeia organised a workshop on the theme "Establishing a Network of Drug Quality in African Countries'.
6. Police swoop on a distributor-changing the expiry date on an energy drink at Accra (CMB)
7. A seminar was held on the dissemination of the Breastfeeding Promotion Regulations Monitoring Report.
8. Police swoop on an illegal medicine manufacturer at Adabraka.
9. Police swoop and media coverage on fake Augmentin tablets distributor

Figure8: Comparison of Communication Activities 2008 & 2009



Source: 2008&2009 communication data

Future Direction

The Food and Drugs Board will continue to confront the challenges presented by the implementation of the Food and Drugs law, 1992 (PNDCL 305B) and its Amendment Act,

1996 (Act 523). In particular, steps will be taken to reinforce the corporate identity of the Board and reposition management for increased commitment to the mandate of the Board. In this regard, the FDB's operational direction for 2010 will focus on the following:

- The decentralization programme for effective implementation and enforcement of the regulatory laws will continue.
- The review of the Tobacco Bill will be completed.
- The human resource situation will be critically examined and recruit qualified staff. Staff motivation will also receive increased attention.
- Staff will receive adequate training and development.
- The review of the Food and Drugs law 1996 (PNDCL 305B) to make it more effective and relevant to the needs of the country and its obligations to the international community will be completed.
- The consumer awareness programmes will continue to ensure public health and safety and consumer confidence. The Laboratory Services will be accredited.
- To put in place a viable Human Resource policy, that will enable the FDB meet its mission.

ANNEX A.1

FOOD AND DRUGS BOARD MANAGEMENT TEAM AND ZONAL OFFICES

Chief Executive	Dr. Stephen Kwabena Opuni
Head of Drug Division	Mrs. Akua Amartey (Acting)
Head of Food Division	Mr. J. Odame Darkwah **(**Acting)

Head of Administration	Mr. Jones Ofosu
Head of Finance	Mr. Kwasi Agyei
Head of Quality Control Laboratory	Mr. Karikari Boateng (Acting)

Office Addresses

Head Office:

Food and Drugs Board
P O Box CT 2783
Cantonments - Accra, Ghana
Telephone: +233-21-235100/233200/225502
Fax: +233-21-229794
URL: http://www.fdbghana.gov.gh
E-mail: fdb@fdbghana.gov.gh

Other Locations

Quality Control Laboratory

Tel: +233-21-673864

Fax: +233-21-667095

Port Offices

Airport: Tel: 021-784653

Elubo: Tel: 0345-22538

Tema: Tel: 022-213418 **Regional/Zonal**

Offices:

Kumasi
Address: The Regional Officer
Food and Drugs Board
P O Box ST 402, Kumasi.
Location: SIC Building 2nd Floor, Bompata, Kumasi
Tel: 051-36070
Fax: 051-36070

Takoradi
Address: The Zonal Officer
Food and Drugs Board
P O Box MC 2129, Takoradi.
Location: SSNIT Regional Offices, (near central Police Station)
Tel: 031-27558
Fax: 031-27558

Bolgatanga

Address: The Zonal Officer
Food and Drugs Board
P O Box 612, Bolgatanga.
Location: Regional Administration Building
Tel: 072-23727
Fax: 072-24590

Ho

Address: The Zonal Officer
Food and Drugs Board
PMB, Ho
Location: Ghana News Agency Building
Tel: 091-65529
Fax: 091-28411

Tamale

Address: The Regional Officer
Food and Drugs Board
Tamale
Location: Regional Administration Building
Tel: 071-24935 Telefax: 071-24889

Sunyani

Address: The Regional Officer
Food and Drugs Board, Sunyani
Location: Sam Bennet Building, Market Square
Tel: 061:28791