2004
ANNUAL REPORT

FOOD AND DRUGS BOARD

NATIONAL BODY RESPONSIBLE FOR THE REGULATION OF FOOD AND DRUGS

FOOD AND DRUGS BOARD
FDB
GHANA

.....Working for your safety

Acronyms and Abbreviations

FDB	-	Food and Drugs Board
FDL	-	Food and Drugs Law
PNDCL	-	Provisional National Defence Council Law
TCB	-	Tobacco Control Bill
NCPP	-	National Consumer Protection Programme
E.U	-	European Union
QCL	-	Quality Control Laboratory
MDL	-	Medical Devices Laboratory
ML	-	Microbiological Laboratory
NCB	-	Narcotics Control Board
GMP	-	Good Manufacturing Practices
MBA	-	Masters in Business Administration
M.A	-	Master of Arts
Msc	-	Master of Science
U.K	-	United Kingdom
HACCP	-	Hazard Analysis and Critical Control Point
IGF	-	Internally Generated Funds
MIS	-	Management Information System
ICT	-	Information and Communication Technology
KIA	-	Kotoka International Airport

EDIF	-	Export Development and Investment Fund
PSI	-	Presidential Special Initiative
ISO	-	International Standard Organization
ADRs	-	Adverse Drug Reactions
WHO	-	World Health Organization
KNUST	-	Kwame Nkrumah University of Science and Technology
cGMP	-	Current Good Manufacturing Practice
GWP	-	Good Warehouse Practice
INCB	-	International Narcotics Control Board
DPMS	-	Drug Post Market Surveillance
FSMU	-	Food Safety Management Unit
GTB	-	Ghana Tourist Board
FRI	-	Food Research Institute
CSIR	-	Centre for Scientific and Industrial Research
NRI	-	Natural Resource Institute
SFV	-	Street Food Vendors
FPMSU	-	Food Post Market Surveillance Unit
GSPP	-	Good Slaughtering and Processing Practices
FPIU	-	Food Premises Inspection Unit
GCP	-	Good Cold store Practices
USAID	-	United States Agency for International Development

MSH	-	Management Science for Health
GC	-	Gas Chromatograph
AAS	-	Atomic Absorption Spectrometry

Note: Bolga and Bolgatanga have been used interchangeably

EXECUTIVE SUMMARY

The year 2004 saw continuing work to consolidate the institutional framework for the establishment of the Food and Drugs Board 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. Work was therefore started on the review of the Tobacco Control Bill and the revision of the Food and Drugs Law. Other policies and guidelines aimed at strengthening the Board to deliver on its mandate were put in place. These included the revision of all guidelines and documents for food and drugs activities and the revision of the fee scheduled of the Board. An inventory of other policies and guidelines already developed, which have implications for the operations of the Board were initiated and steps were taken to review them.

During the year, a 15-member Governing Board was inaugurated, which is chaired by Professor G. D Lutterodt, a retired Professor of Pharmacology.

The National Consumer Protection Programme started in earnest with the acquisition of seven Ford Ranger pick-ups. A range of activities including Media and Television programmes were outlined during the year to guide the Board and the Zonal Offices in support of the consumer protection programme to protect public health and safety.

Applications for import permits received during the year dropped by 22.0% whilst the total registration and licensing activities increased by 31.4% over 2003 figures. Other activities like inspections saw a significant increase. There was an improvement in the operations of the Zonal Offices including an increase in revenue generation. The Board extended its regulatory control to the exportation of palm oil to the European Union during the year. The Board continued its decentralisation policy for the implementation of its mandate. Apart from three (3) functional Zonal Offices, the Board opened one more Zonal Office in Ho during the year bringing the total number of Zonal Offices to four (4). Establishment of an office at Elubo, a border town on the western frontier between Ghana and La Cote D'Ivoire, was initiated for official commissioning in 2005.

The Quality Control Laboratory testing capacity was enhanced with the construction and equipping of two more units, namely Medical Devices Laboratory and Microbiological Laboratory.

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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 Setting up and History

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

1994 (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 Our 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 The 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 The Mission Statement and Goals

The 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 Board has set for itself the following goals:

The Board 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 self-development, 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.

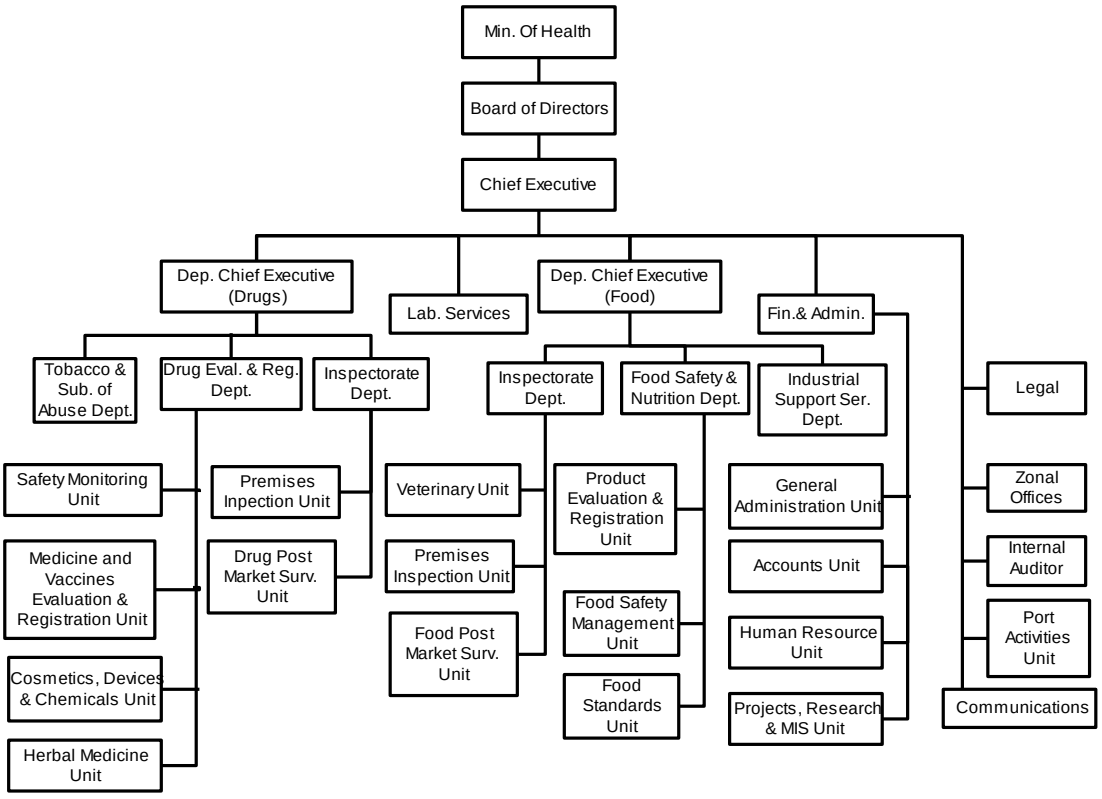
The Food and Drugs Board has been without a Governing Board since October 2000, until 4th August 2004 when a 15-member Governing Board was inaugurated. The new Governing Board is chaired by Professor G. D Lutterodt, a retired Professor of Pharmacology. The members of the Governing Board are listed below.

Prof. G. D. Lutterodt	Chairman, Retired Professor in Pharmacology Kwame Nkrumah University of Science and Technology, Kumasi and University of Malaysia.
Mr. E. K. Agyarko	Chief Executive, Food and Drugs Board.
Mr. John Pwamang	Environmental Protect Agency.
Mr. M. F. Awuku-Kwatia	Registrar, Pharmacy Council.
Dr. A. W. Plahar	Director, Food Research Institute.
Mr. S. D Manu	Fisheries Dept., Ministry of Food & Agriculture.
Dr. Mensah Agyen-Frimpong	Director, Veterinary Services.
Mr. I. F. Jackson	Crop Services, Ministry of Food and Agriculture.

Mr. L. E. Yankey	Ag. Executive Director, Ghana Standards Board.
Dr. Francis Ofei	Ghana Medical Association.
Ms. Felicia Otchere-Darko	Attorney General's Department.
Prof. E. Asibey-Berko	Dept.of Nutrition & Food Science, Uni. of Ghana.
Kuro Kuri-Bukite Liman IV	Paramount Chief of Gwollu, Representing Consumers
Ms. Rubina Amarteifio	Business Woman, Cape Coast. Representing Consumers.
Mr. Kenneth Danso	Traditional Medicine Practitioner.

1.7 The Organisational Structure

The current functional organogram of the Board is indicated below:



In summary, the Board 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 have very grave consequences on public health and serious implications for healthcare delivery. The Board, 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 2004.

FINANCE AND ADMINISTRATION

The Finance and Administration Department of the Food and Drugs Board is the support service wing of the Board. The Department provides services in the areas of General Administration, Accounts, Human Resource management, Transport, Estates management, Communications, Legal, Projects, Research and Management Information System, and Security.

2.1 Personnel and Administration Unit

The year 2004 saw in its wake, the continuation of capacity building in human resource base, with the staff strength increased from 118 to 130. A summary of staff complement as at the end of December 2004 stood as shown below:

Pharmacists	30
Biochemists	14
Food Scientists	6
Chemists	6

Biologists	2
Botanist	1
Veterinary Surgeon	1
Operations Research Scientist/MIS	1
Agricultural Scientists	3
Laboratory Technologists	7
Laboratory Technicians	2
Secretaries	12
Accountants	3
Internal Auditor	1
Clerks	3
Administrative Assistants	4
Administrative Officers	2
Store Manager	1
Drivers	13
Communications and PR personnel	3
Lawyer	1
Security Guards	14
Total	**130**

2.1.1 Human Resource Development

During the year under review, the Board received government approval to recruit additional 50 staff for the year 2005. In response to advertisement placed in the press by the Board, 243 applications were received out of which 119 were short-listed for interview. 104 applicants were interviewed for the following positions: Regulatory Officers, Assistant Regulatory Officers, Laboratory Technologists/Technicians, Accounts Officers, Administrative Assistants, Secretaries, Drivers, Auditors and Security personnel. Successful applicants were offered jobs to assume duty in February and March 2005, respectively.

To enhance the skills of the staff through short, medium and long term training courses, one staff benefited from a Japanese government scholarship to attend a three-month

training in Food Quality Assurance in Tokyo. Two members of staff obtained Ghana government scholarship for a year's Master of Science in Food Science in University of Reading and Master's in Communication Studies in Cardiff, UK. The Board sponsored two other very senior officers to undertake MBA programmes in Public Administration and Entrepreneurship. Two members of staff returned from the UK after successful completion of courses in MA in Communication Studies and M.Sc. in Food Safety, respectively. In addition, ten staff benefited from short term courses and overseas training in various disciplines such as Certificate in Public Administration, Laboratory Management, Pharmacovigilance, Drug Counterfeiting, Dissolution Testing and UV Spectroscopy.

2.1.2 Capacity building

The Board continued its decentralization and capacity building programmes in order to improve upon its service delivery. To this end, the Volta Regional Office was opened in Ho on 1st July 2004 to extend the services of the Board to the Volta and Eastern Regions of Ghana. Establishment of an office at Elubo, a border town on the western frontier between Ghana and La Cote D'Ivoire, was initiated for official commissioning in 2005. The Quality Control Laboratory testing capacity was enhanced with the construction and equipping of two more units, namely Medical Devices Laboratory and Microbiological Laboratory.

The plans toward the construction of a new Head Office/ Laboratory Building Complex took a giant leap forward with the advertisement in the print media Invitation to Tender, which sought to obtain quotations from prospective contractors and consequent selection and award of contract. The Board also purchased a residential accommodation for its Northern Zonal Office in Bolgatanga.

To enhance its inspection activities, the Board acquired seven Ford Ranger pick-ups and one Toyota Land Cruiser cross country vehicle. Three saloon cars were also purchased

for official use by top management. Five motorcycles were given to the Board by the government through the Ministry of Health.

In-house training and training in local institutions in the areas of Management, HACCP, HACCP Audit, Defensive Driving and computer applications were organized for staff.

2.2 Finance and Accounts Unit

The main sources of external funds for the Board are government subvention and grants provided through donor-pooled funds from the nation's development partners. The bulk of the Board's revenue is internally generated through product registration fees, import permit fees, manufacturing licensing fees, product advertisement fees, sale of registration forms, destination inspection fees, expired/unwholesome products destruction fees, and drug analysis fees. The internally Generated Funds (IGF) have been the mainstay of support for the Board's decentralization and regulatory programmes.

During the year, Ghana Government support for the Board's consumer protection activities was boosted with a budgetary allocation of 13 billion Cedis.

The financial accounts of the Board are audited annually by the Auditor General's Department.

2.3 Legal Unit

The Legal Unit provides legal services to the Board and secretarial support to the Governing Board. The Board currently has a draft Bill for both Tobacco Control and the Food and Drugs Regulations.

2.4 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 various media programmes particularly with respect to consumer education, media coverage of the Board's activities and publication of health alerts and press releases for the information of the public and the international community at large.

During the year under review, the press releases and health warnings that were issued among the Media Houses are shown below.

Area of Activity	**Frequency**	**%**
Press Release	21	34.4
Media Coverage	13	21.3
Media Interviews and Programmes	27	44.4
Total	**61**	**100.0**

Figure 1 shows comparative activity for 2003 and 2004.

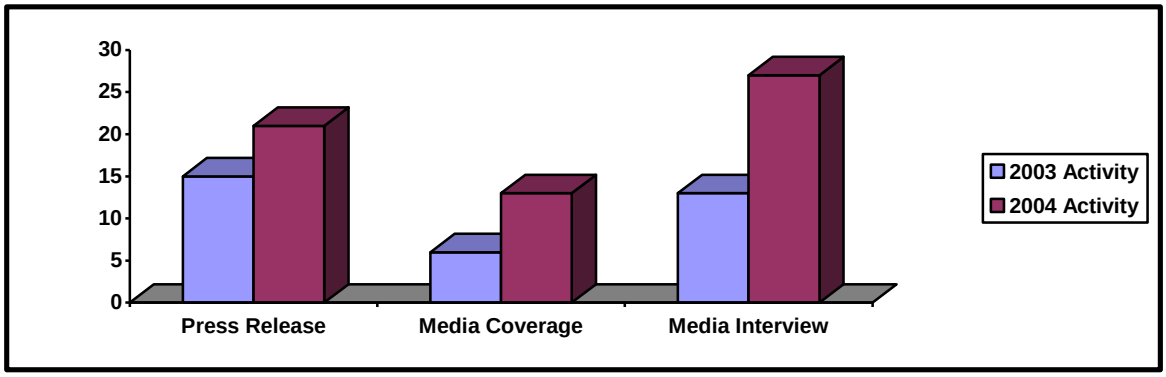


Fig. 1 Comparison of Communications Activity for 2003 and 2004

2.5 Projects, Research &MIS Unit

This Unit was set up to play the roles of a co-ordinating centre for projects and research activities within the Board, and 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 (ICT).

During the year, two operations software and the website for the Board were developed. The Unit undertook the development of five project proposals. The table below shows the details of activities conducted by the Unit.

No.	Area of Activity	Purpose	Submitted To	Status
1	Developed Human Resource Management software	To ensure effective staff management	Head, Finance and Administration	Functional
2	Developed Destination Inspection software	To capture and generate MIS reports on regulated imports	KIA and Tema Port Offices	Functional
3	Developed FDB Website	To disseminate information on the activities of the Board	FDB Management	Yet to be hosted
4	Developed the Roadmap for implementing Quality Management System ISO 9001: 2000	To install quality management system in FDB	FDB Management	Yet to be implemented
5	Developed Proposal on National Consumer Protection Programme	To assure public health and safety and consumer confidence.	Min. of Finance & Economic Planning	Implemented and on-going
6	Coordinated Export Development and Investment Fund (EDIF) project	The project was meant to position Food and Pharmaceutical Industries with potential to export to improve their export potentials	EDIF	Completed
7	Proposal on Equatorial Guinea Joint	Training in Regulatory functions and	Min. of Trade & PSI	Pending

	Commission	Laboratory Analysis		
8	Gateway Retrofitting Project	Request for support in capacity building, ISO 9000 certification implementation programme and Laboratory Accreditation	Gateway Secretariat	Pending
9	Recommendations for Food Audit Inspection Fees	To establish appropriate registration fees for selected food products	FDB Management	On-going

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. This is 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 two specialized departments and supported by six operational units.

3.1 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

3.1.1 Medicine and Vaccines Evaluation and Registration Unit

The main functions of Medicine and Vaccines Evaluation and Registration Unit are:

- To register drug products and issues certificates:
  Assessment of applications for the registration of medicine 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 information provided on packages and package inserts are correct and adequate to enable the Board take the appropriate decision.
  - Active maintenance of SIAMED Database.

Product registration meetings are held on monthly basis to review applications for product registration.

During the year under review, 2,078 applications were received and 1,518 were registered. Table 1gives the summary of the breakdown of applications processed and registered by the Unit in 2004.

Table 1: Breakdown of Applications Processed and Registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Allopathic (orthodox) Drugs	766	179	576	99

Veterinary Drugs	232	-	190	-
Herbal Drugs	90	95	54	44
Cosmetics	311	41	237	16
Household Chemicals	86	12	55	8
Medical Devices	161	3	131	1
Food Supplements	99	3	105*	2
Vaccines	-	-	-	-
Total	**1,745**	**333**	**1,348**	**170**

* 6 processed applications brought forward from December 2003 and approved in 2004

3.1.1.1 Product Advertisement

The Unit also performs assessment of applications for drug promotional materials. The assessment of advertisements involves the following:

- Vetting of scripts submitted for advertisement to ensure that content is acceptable to the Board.
- Evaluation of audio and video cassettes to ensure conformance to vetted scripts.

In 2004, the Unit vetted 206 advertisement applications in various categories and approved 65. Table 2 gives the summary of advertisements processed in 2004 and Fig. 2 shows the distribution of product advertisement among media houses.

Table 2: Advertisements Received and Processed in 2004

Area of Advert	No. of Applications	Number Approved
Allopathic (orthodox) Drugs	95	32
Herbal Drugs	65	17
Cosmetics	27	8
Household Chemical	10	6
Food Supplements	3	1
Medical Devices	6	1
Total	**206**	**65**

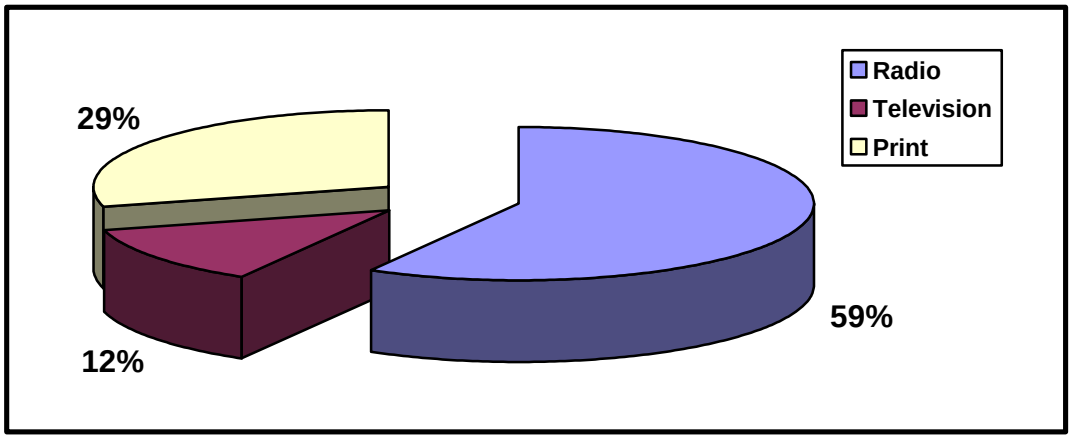


Fig. 2: Distribution of Product Advertisement among Media Houses

3.1.1.2 Import Permits

The issuance of import permit for drugs is one of the major functions of the Unit. The assessment of applications for import permit involves the following:

- Ensuring that products to be imported have valid registration numbers.
- Names of products and their respective quantities stated in invoices tally with information provided in application forms.
- Ensuring that application submitted is acceptable to the Board

During the year, the Unit processed a total number of 2,280 import permits covering the following products: finished products, pharmaceutical raw materials, hospital supplies, donations and prescriptions for personal use. Table 3 shows the summary of import permits processed from January to December 2004.

Table 3: Summary of Import Permits Processed in 2004

Month	Finished Products	Raw Materials	Hospitals	Donations	Personal Use	Total
January	150	73	7	1	-	**231**
February	125	67	7	-	-	**199**

March	149	100	17	1	-	**267**
April	66	49	5	-	-	**120**
May	111	44	4	2	-	**161**
June	122	67	3	1	-	**193**
July	110	70	5	-	-	**185**
August	122	63	6	1	3	**195**
September	122	68	7	4	-	**201**
October	115	53	1	5	-	**174**
November	126	66	-	1	-	**193**
December	103	57	-	-	1	**161**
Total	**1421**	**777**	**62**	**16**	**4**	**2280**

Fig. 3 shows comparative monthly total number of import permits processed for 2003 and 2004.

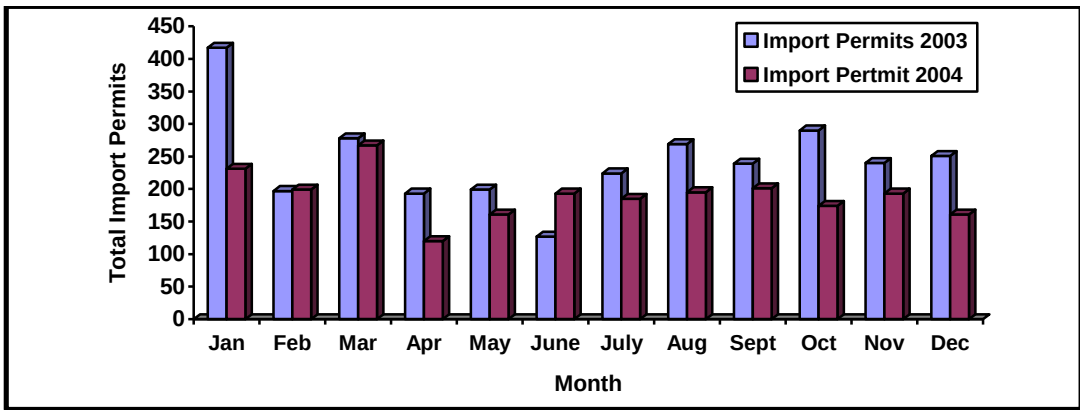


Fig. 3: Comparison of monthly Total Import Permits issued for 2003 and 2004.

3.1.2 Safety Monitoring Unit

The Safety Monitoring Unit was set up during the year under review with the following functions:

- To collaborate with the Drug Post-Market Surveillance Unit to monitor Adverse Drug Reactions (ADRs).
- Promotion of spontaneous reporting of Adverse Drug Reactions (ADRs) and adverse effects following immunisation in the country.
- Assessment and validation of completed ADR case report forms and onward submission to the WHO collaborating Centre for International Drug Monitoring known as Uppsala Monitoring Centre.
- Communication of drug-related problems and recommended 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).
- Serve as Product Information Centre.
- To collaborate with local stakeholders and professional associations.

During the year under review, none of the Unit's functions was undertaken because there was no staff to handle the Unit. However, in July 2004 a new Unit Head was appointed to carry out the activities of the Unit. The Unit was therefore occupied with proposals writing on the new direction for the Unit. A training programme on a Study of Adverse Reactions organised by Therapeutic Goods Administration (TGA) in Australia was attended by the Unit Head.

3.1.3 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, KNUST-Kumasi, and Department of Pharmacology, Korle-Bu Teaching Hospital
- Products that are recommended for registration are issued with registration number, which are valid for one (1) year in case of locally manufactured products and three years for imported herbal drugs.

During the year under review, 90 foreign and 54 local herbal products were evaluated. Out of these numbers, 54 foreign and 44 local herbal products were registered, respectively.

3.1.4 Cosmetics, Household Chemicals and Medical Devices Unit

The Unit's main functions are:

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

The table 4 below and Fig. 4 show the number of products received and registered during the year under review.

Table 4: Summary of products received and registered in 2004

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Cosmetics	311	41	237	16
Household Chemicals	86	12	55	8
Medical Devices	161	3	131	1
Total	**558**	**56**	**423**	**25**

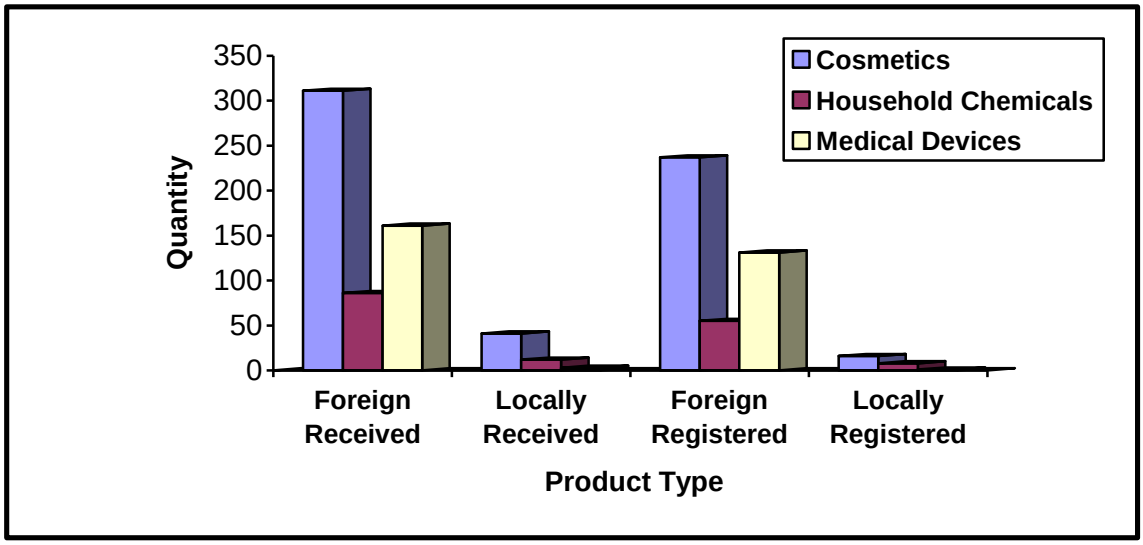


Fig. 4: Products Type Received and Registered in 2004

3.2 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

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

3.2.1 Premises Inspection Unit

The principal functions of Drug Premises Inspection Unit are:

- Conducting routine audit inspections of all the pharmaceutical manufacturing companies that are registered with the Board to ensure compliance with current Good Manufacturing Practice (cGMP), and Good Warehouse Practice (GWP).
- Conducting routine GMP inspection in pharmaceutical, herbal, cosmetics and household chemical manufacturing companies.
- Conducting external Good manufacturing Audit inspections of pharmaceutical industries carrying out business in Ghana.
- Conducting capacity monitoring and control of extemporaneous preparations.

During the year under review, 17 local pharmaceutical companies, 36 herbal manufacturers and 9 cosmetics industries were inspected as part of product registration and pre-licensing of premises requirements. The Unit was able to conduct routine audit

inspections of all the 62 manufacturing companies that were registered. Generally, the findings of the inspections indicated improvement in Good Manufacturing Practice.

Regulatory sanctions were instituted against 7 pharmaceutical companies for non-compliance to total quality assurance systems and re-location.

Capacity monitoring to ensure that the total national production and sale of locally manufactured pharmaceutical products are compiled and assessed by the Board were not effective since the companies involved did not comply or cooperate.

The Unit reviewed 7 guidelines and forms to bring them into conformity with the current trends and best international practice during the year under review.

3.2.1.1 External Good Manufacturing Practice (GMP) Audit Inspections

Overseas GMP audit inspections of Pharmaceutical Companies carrying out business in Ghana were carried out during the period under review.

In 2004, 20 pharmaceutical manufacturing facilities were inspected, out of which 16 were found to be Good Manufacturing Practice (GMP) compliant while 4 companies were found to be GMP non-compliant. The list of approved companies as at September 2004 has since been published in the National Dailies.

Fig. 5 shows Good Manufacturing Practice (GMP) compliant companies the team inspected in 2004.

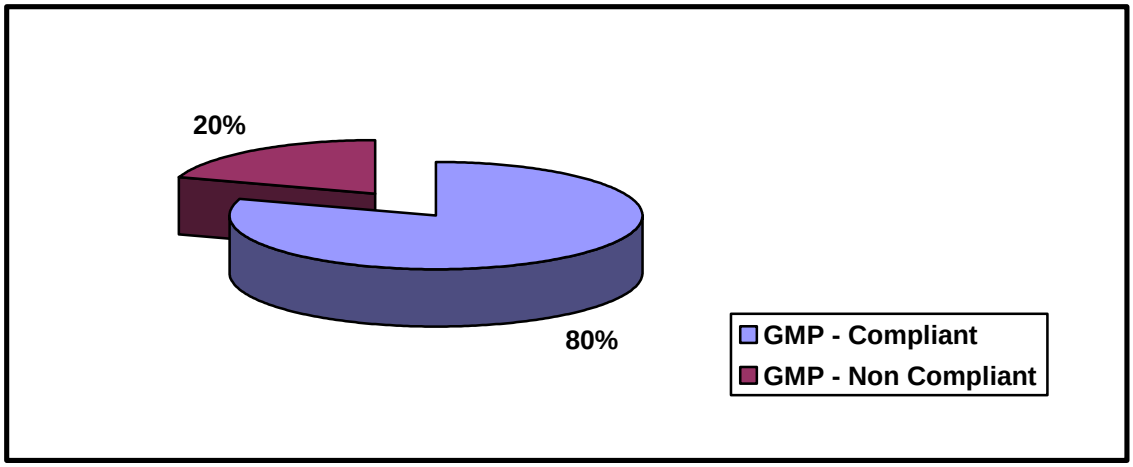


Fig. 5: GMP–Compliant Companies

3.2.1.2 Inspections of Local Cosmetic and Household Chemicals Manufacturing Industries

Local companies manufacturing cosmetics and household chemicals were inspected as a pre-requisite to the listing of their products. During the year under review, only 5 medium-size companies were licensed by the Board for meeting of the pre-licensing requirements.

3.2.2 Drug Post-Market Surveillance Unit

The Unit monitors medicines, cosmetics, medical devices and household chemicals for ensuring public health and safety and consumer confidence. The activities of the Unit start when market authorization has been granted to the importer.

The major functions of the Unit include:

- To collaborate with Pharmacy Council to continuously monitor quality of products on the Ghanaian market.
- To conduct operational research on products registered by the Board on the Ghanaian market.
- To monitor products on the Ghanaian market for registration, expiry date, and labelling to conform to established rules.
- To liaise with Port Offices to monitor drug and other product donations.

- To reconcile inventory and perform destruction of expired products.
- To monitor and review drug promotion and advertising
- To monitor storage facilities of clinics, hospitals, central medical stores and regional medical stores.
- To investigate issues on consumer complaints and counterfeiting.

A proposal to seek the joint collaborative functions of the Pharmacy Council and the Board in the area of product quality monitoring and the development of a system of reporting on defective, spurious, substandard and counterfeit drugs was initiated. During the year under review, work on the joint collaborative functions started with the identification of eight key areas of operation for implementation. The areas were

- Inspection and Monitoring
- Advertisement
- Resource mobilisation and use
- Public Education
- Licensing of facilities and product registration
- Joint operations research
- Exchanging information
- Herbal Medicines

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

- Investigation of 26 consumer complaints and drug counterfeiting. The appropriate regulatory measures were initiated to forestall the situation.
- 12 warehouse inspections were successfully carried out on importers and wholesalers of pharmaceutical products in accordance to Good Warehouse Practices (GWP).
- Ensuring the removal of spurious and substandard drugs from the market as part of product quality monitoring. With the support of the Regional Police Command, illegal producers of locally made cosmetics were flashed out.
- 2 herbal medicinal products were refused registration due to failure in laboratory analysis test.

- Upon the Unit investigations, the Board banned some unidentified brand of ephedrine tablets. Paludose (dihydroatermisinin) tables were also refused registration due to failure to pass dissolution test.
- The Unit supervised the destruction of unwholesome and expired pharmaceutical products from 16 pharmaceutical companies and certificates of destruction were issued accordingly.
- The Unit also monitored unapproved drug promotional materials and 15 such companies were found to violate the Board's requirements.

3.2.2.1 Narcotics and Psychotropic Substances

The Board regulates the importation and use of narcotics and psychotropic substances by means of a permit system. The importing companies have to furnish the Board with advice of receipt, annual returns, and the requisitions for the ensuing year. The Board also receives multilateral chemical reporting notification forms for endorsement in connection with the importation and control of precursors. The Board also sends quarterly and annual returns on the use and importation of narcotics and psychotropic substances to the International Narcotics Control Board in Vienna. All these functions are carried by the Drug Post-Market Surveillance Unit (DPMS).

In 2004, the Board issued 64 permits to 27 companies. Out of this number, 24 permits were for raw materials that were issued to 10 companies and 40 permits were for finished products, which were also issued to 17 companies. However, two companies were refused permits due to some regulatory measures. The Board also received 14 export Authorisation Forms for endorsement.

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 carry out by evaluating all samples submitted in the registration process, 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. Moreover, the Division ensures that all imported and locally produced food products are of good quality and wholesome.

The activities of the Division are carried out by 2 specialized departments and supported by 6 operational units.

4.1 Food Safety and Nutrition Department

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

- Food Product Evaluation and Registration Unit.
- Food Standards Unit
- Food Safety and Management Unit.

4.1.1 Food Product Evaluation and Registration Unit

The principal functions of the Unit include:

- Registering food products.
- Evaluating food product labels to ensure conformance to the labelling law.
- Conducting evaluation meetings for food product approval.

In 2004, a total number of 1,063 products were submitted to the Board for registration. Out of this number, 258 representing 24.3% were locally manufactured whilst 805 representing 75.7% were imported (foreign). Table 5 gives the summary of food products submitted and registered by the Unit.

Table 5: Summary of Food Products Submitted and Registered in 2004

Product Category	Imported (Foreign)	Registered (Foreign)	Manufactured Locally	Registered (Locally)
Drinks	226	178	67	40
Fats and Oils	54	34	5	-
Confectionery	235	110	12	1
Packaged Water	2	-	124	44
Fish/ Fish Products	26	22	-	-
Diary and Diary	34	25	8	4

Products				
Additives	59	56	9	7
Meat and Meat Products	18	12	1	-
Roots and Tubers	6	6	9	3
Fruits	5	4	-	-
Cereals	73	66	13	9
Vegetables	64	46	10	3
Pet Food	4	1	-	-
Total	**806**	**560**	**258**	**112**

During the year under review, 390 food products were deferred for one or more of the following reasons:

- Incomplete address of manufacture
- No country of origin
- Absence of name and address of manufacture
- No date of minimum durability
- No batch number
- Misleading labelling/claims
- No net weight
- Presence of foreign matter
- Faulty can lining
- Faded Labelling
- Wrongly declared content
- Ingredient not specified
- No stability data supporting long shelf life of product
- Labelling not in English

Fig. 6a and 6b show the comparison of the number of foreign and local food products, submitted, registered and rejected in 2003 and 2004, respectively.

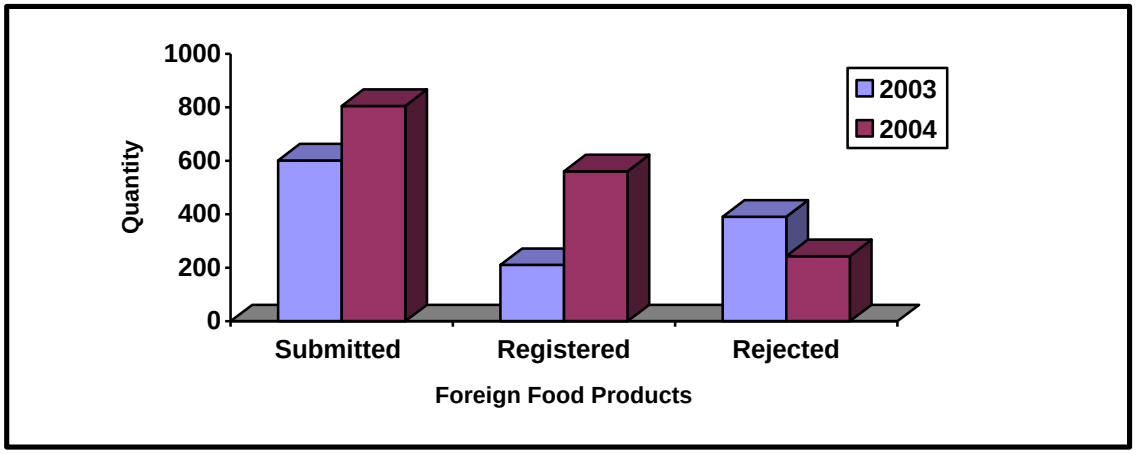


Fig. 6a: Comparison of Foreign Food Products Processed, Registered and Rejected in 2003 and 2004

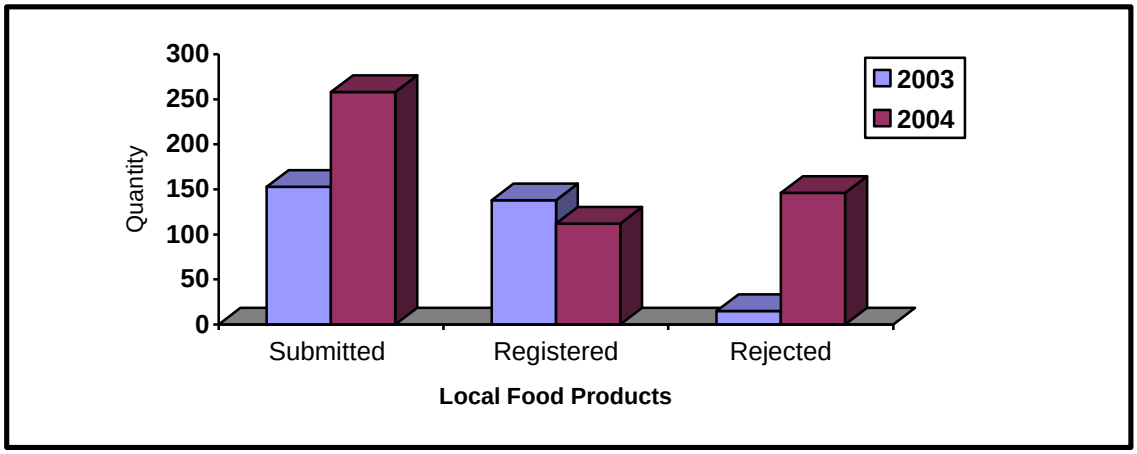


Fig.6b: Comparison of Local Food Products Processed, Registered and Rejected in 2003 and 2004

4.1.2 Food Standards Unit

The Unit was set up in the last quarter of 2003. Since its inception, the Unit has been manned by one staff member. The principal objectives of the Unit are to make available the appropriate food standards and developing Guidelines and Codes of regulations to augment the work of the Food Division.

The specific objectives of the Unit are:

- Specifying what constitutes adulteration of any food.
- Prescribing the type and level of food additives permitted in food.
- Providing information to other Units under the Food Division on the status of Food Additives or any substance used as an ingredient in any food.
- Prescribing methods of manufacture, processing, sale, storage and transportation of food.
- Prescribing the parameters or attributes to be included in food registration forms.
- Prescribing means of protection of the consumer or purchaser of food from being deceived or misled as to its quality, character, composition, merit or safety or to prevent injury to the health of consumer or purchaser
- Periodically organizing seminars for officers under the Food Division as a means of educating or keeping them abreast on issues pertaining to food safety and food regulation.
- Ensuring the availability of relevant food standards or reference documents to facilitate the evaluation of food products by the Food Evaluation and Registration Unit.

During the year under review, the Unit acquired twenty-seven (27) Ghana Food Standards, which had been developed and published by the Ghana Standards Board. Electronic copies of all Codex Standards were acquired and printed copies were made available to the Food Division, when needed. Four (4) seminars were organised to support the work of the Food Division.

The Unit also collaborated with other Food Departments and Units to review Guidelines to streamline the activities of the Food Division. In 2004, 14 Guidelines were reviewed and 12 Food Forms were updated to meet current requirements. The Unit also assisted other Food Units in developing and finalising discussions on 16 Standard Operating Procedures (SOPs) for the Food Division.

4.1.3 Food Safety Management Unit

The Food Safety Management Unit (FSMU) became operational from March 2004 as part of the Food Safety and Nutrition Department. It has since been actively involved in execution of the following functions:

- Assisting local food manufacturers/processors in the implementation of food safety management system such as the HACCP system.
- Conducting Food Safety Audits.
- Conducting training programmes for food manufacturers or processors, staff of the hospitality sector, catering schools etc.
- Conducting activities to create food safety awareness among consumers.
- Representing the Board on stakeholder committees on food safety.
- Investigating consumer complaints.

In 2004, the Unit successfully organised the Second National Food Safety Week in Kumasi as part of the food safety awareness creation campaign. The Unit was also involved in a Needs Assessment Project involving sixteen (16) Food Processing Companies with the potential to export, (Export Development and Investment Fund project).

During the year, the following facilities were audited by the unit:

- The BonAqua plant of the Coca Cola Bottling Company of Ghana Limited (CCBGL),
- Allied Cocoa Products
- Accra Breweries Ltd
- The canteen of Ghana International School.

In addition to the above audit inspection, the Unit extended the exercise to 59 restaurants within the Accra Metropolis, which yielded good results. Following the completion of the restaurant audit exercise, a sensitization workshop was organised for management of restaurants and fast food joints in the Greater Accra Region. The Ghana Tourist Board was actively involved in the workshop.

4.1.3.1 Training Programmes and Workshops

The Units organises training programmes as part of its work programme. This is conducted in collaboration with other Units, Departments and Institutions. In 2004, the Unit organised or was part of the following training programmes:

- Two weeks training for Traditional Caterers and Food Handlers in the Nzema East and West districts.
- Participated in three training programmes for Traditional Caterers (Chop Bar operators) organised by the Ghana Tourist Board (GTB) that took place at Accra Central, Pig Farm and Medina Areas.
- In collaboration with the Food Research Institute (FRI) of the Centre for Scientific and Industrial Research (CSIR) and the Natural Resources Institute (NRI) of the University of Greenwich, U.K a training programme was organised for Traditional Caterers and Street Food Vendors (SFV) in the Accra-Tema Metropolitan areas.
- The Unit was involved in the training programme organised for owners and operators of Warehouses/Cold Stores by the Food Post Market Surveillance Unit (FPMSU).
- The Unit provided resource persons in two workshops organised by the Ghana Public Private Partnership for Food Industry Development.
- Sensitization programmes on food safety were organised for two (2) Church groups (Church of Pentecost Women Fellowship, Kaneshie and Presbyterian Church of Ghana, Tema Community 8) during the year under review.

4.1.3.2 Consumer Complaints

During the year, the Unit handled 13 consumer complaints. The major problems arising with consumer complaints have to do with the handling of complaint samples and forms from Head Office to Anchor house. The situation hampers investigations.

4.1.3.3 Palm Oil Screening for Sudan IV Dye

In 2004, the Unit in collaboration with the Food Standards Unit developed guidelines for the export of palm oil and published them in the local dailies. In all 83 consignments of palm oil were sampled and analysed during the year under review. Out of this number, 25 samples failed, representing 30.1%. 54 samples of the palm oil screened were of the regular type (Virgin Palm Oil) and 29 were "Zomi". Thirteen 13 samples of the regular palm oil failed (24.07%). Of the 29 "Zomi" samples screened, 12 samples (41.38%) were found to contain the Sudan IV dye. The conclusion was that there was a higher failure rate for the "Zomi" palm oil as compared to the regular palm oil.

Another observation made shows that out of the 36 companies whose products were screened, 14 of them had all or some of their samples tainted with Sudan IV dye on first screening representing 38.9%. Out of the 14 companies, 4 companies have made subsequent attempts to export their samples, which is free from the Sudan IV dye when tested.

4.1.3.4 Food Alerts

Since October 2004, none of the palm oil consignments that were analyzed and issued with Export Permits has been implicated. This indicates that the screening and permit system has been successful.

Before October 2004, 76 food alerts on palm oil were received. All the alerts received indicated adulteration of the palm oil samples. Also some of the implicated samples do not bear Batch Codes and/or traceable Ghanaian addresses, instead foreign addresses of packers.

The screening exercise conducted so far for Sudan IV dye on palm oil samples meant for export has yielded positive results; however, giving the fact that there was an initial high

detection rate in palm oil sampled, the likelihood that the palm oil on the local market is contaminated with the implicated dye is high.

The Unit was also involved in the National palm oil survey conducted for Sudan IV screening. In all four hundred and eighty four (484) samples were collected nationwide. These samples have since been submitted to the laboratory for assessment.

4.1.3.5 The Challenges

- A major challenge impacting negatively on the screening programme is often the undue delay that characterizes the analysis of the samples at the laboratory. This tends to disrupt the schedules of the exporters.
- Another challenge confronting the programme is the monitoring and disposal of consignments of samples that have failed.
- Lack of appropriate pack houses for bottling palm oil and poor adherence to Good Manufacturing Practices (GMP) are issues that need to be addressed.

4.2 Food Inspectorate Department

The Food Inspectorate Department under the Food Division is 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 that they conform to current Good Manufacturing Practices.

The functions of the Department are carried out by the following operational Units:

- Veterinary Unit
- Premises Inspection Unit
- Post-Market Surveillance Unit

4.2.1 Veterinary Unit

The major functions of the Unit are:

- Registering slaughter facilities.
- Licensing feed mills.
- Inspecting feed mills' warehouses to ensure Good Warehouse Practices (GWP), and Good Manufacturing Practices (GMP).
- Inspecting slaughter facilities to ensure Good Slaughtering and Processing Practices (GSPP).
- Inspecting veterinary drugs warehouse to ensure Good Warehouse Practices (GWP).

In line with its functions, the Unit safeguarded public health by enforcing applications of the relevant sections of the Food and Drugs Law (PNDCL 305B) and its amendment Act 523 of 1996.

The main activities carried out in 2004 were inspections of Abattoirs and slaughter slabs, monitoring of poultry and meat products in major supermarkets. The Unit also conducted sensitisation programmes for butchers and was part of the various educational programmes organised by the Board.

4.2.1.1 Specific Activities Undertaken

During the year under review, the Unit undertook the following activities:

- Organised a six-week sensitisation programme for all butchers in Accra-Tema Metropolis. The butchers were educated on the Food and Drugs Law, the importance of ante- and post-mortem inspections, the dangers in singeing animals using lorry tyres and transporting of carcass in rickety vehicles/taxi boots. Furthermore, the butchers were educated on the need for the food handler's test and the need to be properly attired in neat uniform. The butchers were also educated on the need to expose people who slaughter at unauthorized places.
- The Unit visited 28 meat markets in Accra Metropolis.

4.2.2 Food Premises Inspection Unit

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

- Inspecting food manufacturing premises for registration.
- Routine inspection of food manufacturing premises to ensure current Good Manufacturing Practices (cGMP).

During the year under review, 147 manufacturing companies were visited and inspected. Table 6 shows the manufacturers and the categories of the food products.

Table 6: Manufacturers and the various food categorisations

Category of Inspection	Manufacturers	%
Water	93	63.3
Diary Products	6	4.0
Vegetables	5	3.4
Drinks	23	15.6
Confectionery	7	4.8
Additives	1	0.7
Fruit	-	-
Catering	1	0.7
Fish and Fish Products	2	1.4
Fats and Oils	2	1.4
Cereals	3	2.0
Root and Tubers	3	2.0
Meat and Meat Products	1	0.7
Total	**147**	**100.0**

Table 7 also shows the level of GMP compliance. Out of 147 manufacturers only 37 representing 25.2 percentage points were granted registration licences. The remaining has to comply with the GMP codes of operation.

Table7: Level of Compliance to GMP

Grading system	Number of companies	Compliance level in %
Excellent	6	4.1
Good	31	21.1
Fair	82	55.8
Poor	24	16.3
Stopped Production	4	2.7
Total	**147**	**100.0**

4.2.2.1 Sachet Water Programme

- This is an on-going exercise to identify the sachet water producing companies. During the year under review, 5 sachet water producing areas in Accra were visted. The general observation was that there were general trends of non-conformance according to GMP codes of practice amongst the water producers.

4.2.3 Food Post-Market Surveillance Unit

The Unit undertakes the following functions to contribute to the achievements of the Food Inspectorate Department:

- Inspecting food storage facilities to ensure their operations conform to Good Warehouse/Cold store Practices (GWP / GCP).
- Inspecting retail outlets and their storage accessories to ensure their operations conform to Good Retail Practices (GRP).
- Monitoring and regulating advertisements of food products
- Destroying unwholesome food products
- Investigating consumer complaints and any other relevant query regarding food products
- Monitoring food product registration and quality status on the Ghanaian market.

In 2004, the Unit inspected 99 warehouses. The details of types of warehouse general inspections are shown in table 8.

Table 8: Types of Inspection Conducted

Month	Type of Inspections conducted				
	Pre-Registration	Routine	Emergency	Follow-up	Total
January	4	1	-	2	7
February	-	6	-	1	7
March	1	4	-	-	5
April	5	1	-		6
May	-	2	-	-	2
June	8	4	-	-	12
July	3	-	1	-	4
August	10	-	-	-	10
September	28	-	-	1	29
October	7	-	-		7
November	5	-	-		5
December	1	-	-	4	5
Total	**72**	**18**	**1**	**8**	**99**

4.2.3.1 Annual Warehouse Inspections in Accra-Tema Metropolis

The Unit organises a month-long warehouse inspections in the Accra-Tema Metropolis annually to ascertain compliance to Good Warehouse Practices (GWP). The programme started in 2004 with the following objectives:

- To ascertain the level of compliance to Good Warehouse Practices.
- To determine the registration status of food products in storage
- To verify if the labelling of prepackaged foods in storage conforms to the General Labelling Rules (LI 1541)
- To determine the physical condition of food products in storage and their best before dates.

During the year, sixty seven (67) warehouses were inspected in Accra-Tema Metropolis. It was observed that the situation with respect to Good Warehouse Practices needs improvement. Other areas of gross non-compliances were records and documentation. No expired products were observed in all the warehouses the team inspected.

4.2.3.2 Inspection of Retail Outlets (Supermarkets)

Inspections of retail outlets in the year under review could not be done at the desired level. This was due to inadequate staff strength and lack of vehicle. However, with the mentioned constraints, the Unit inspected 21 supermarkets during the year under review.

4.2.3.3 Pre-Christmas Supermarket Inspections

During the year, 16 major supermarkets in Accra were visited. 47% of the supermarkets inspected had displayed a wide range of expired food products for sale. Most of these were imported food products, very few local expired food products were observed.

4.2.3.4 Food Product Monitoring

In pursuance of the provisions of Food and Drugs Law 305B, 1996, all importers and local manufacturers of food products are to register their food products with the Food and Drugs Board. Although the Board has made this known publicly many food importing and manufacturing companies still flout the above directive.

After so much education on the need for registration of all food products with the Board, a large number of unregistered food products are still flooding the markets. In 2004, 13 locally manufactured and 9 imported food products were picked on the open market with the aim of bringing the activities of those companies that manufacture or import these food products into compliance.

4.2.3.5 National Palm Oil Quality Monitoring Exercise

Frequent food alerts were received from the European Union concerning the quality of Ghanaian palm oil specifically, the adulteration of its colour by the use of the Sudan IV dye, which is banned due to its carcinogenic tendencies. The adulteration of the palm oil is due to the preference for its inherent bright red colour by consumers.

In a bid to protect the health of the Ghanaian consumers and the name of the country abroad, the Unit was part of a team in 2004 that undertook the exercise of ensuring the safety and quality of palm oils produced in the major producing areas in Ghana.

During the year of the exercise, 448 samples were collected nation-wide for laboratory analysis. One significant observation made was that majority of palm oils producers in Ghana are small scale.

4.2.3.6 Consumer Complaints

As part of its functions, the Unit investigated 20 consumer complaints during the year under review. Out of this number, 15 complaints were appropriately acknowledged.

4.2.3.7 Processing of Advertisement applications

During the year under review, 45 advertisement applications were received. Out of this number of applications, 38 or 81%were approved. The applications that were not approved were due to the fact that the products had not been registered or the applicants were asked to make some corrections on the script. Fig. 7 shows the status of advertisement received during the year under review.

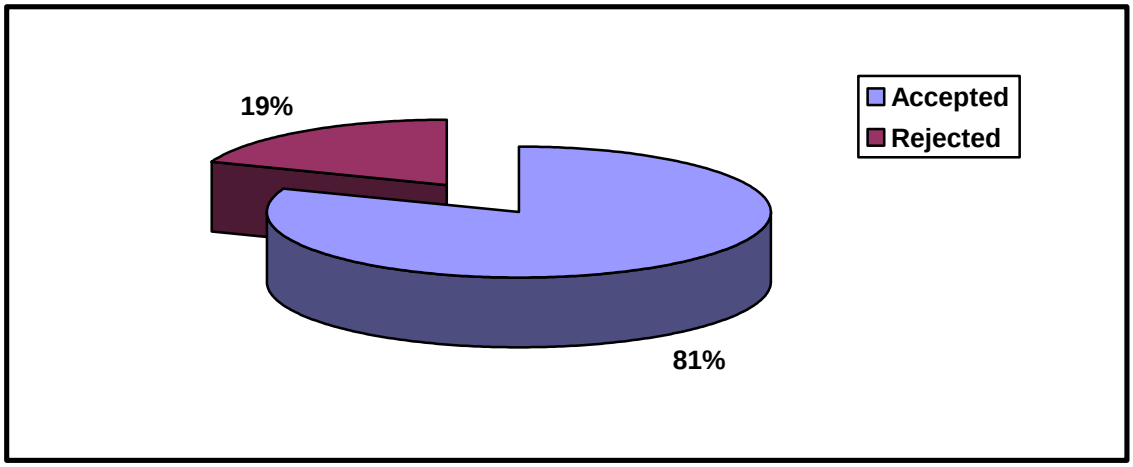


Fig.7: Status of Product Advertisement received in 2004

Table 9 shows the monthly applications received during the year under review.

Table 9: Monthly distribution of applications received in 2004

Month	**Number of Advertisement Applications received**
January	1
February	3
March	12
April	1
May	2
June	4
July	2
August	4
September	5
October	7
November	1
December	3
Total	**45**

4.2.4 Monitoring of Destruction of Unwholesome/Expired Food Products

In 2004, 12 destructions were monitored. Out of the number of destructions monitored, two of these were compulsory. The reasons for the destructions range from insects infestation, expired dates, and banned products like turkey tails.

4.2.4.1 Warehouse Training Workshop

The Unit organised a two day training workshop for warehouse operators and managers, which was attended by 29 participants from various companies and was well publicised in the media.

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.

During the year under review, 3696 samples were received. These were made up of allopathic drugs (33.1%), cosmetics (11.0%), food (44.6%), herbal drugs (5.3%) and veterinary drugs (6.0%). Table 10 gives the summary of product categories received for the various analytical tests.

Table10: Summary of Product Categories Received and Analysed

Sample Category	Received	Analysed	Not Analysed	Passed	Failed
Allopathic Drugs	1,222	1,076	146	1,002	75
Herbal Drugs	196	193	3	137	56
Veterinary Drugs	223	127	96	127	-
Food	1,648	1,549	99	1,493	55
Cosmetics	407	399	8	394	5
Total	**3,696**	**3,344**	**352**	**3,153**	**191**

Table 11 shows the summary of total sample analysed and their sources.

Table 11: Distribution of Total Samples Analysed and their Sources

Source	Received	Analysed	Not Analysed	Passed	Failed	% Source

Drug Evaluation & Registration	1683	1417	266	1358	59	45.5
Inspectorate/PMS	105	97	8	82	15	2.8
Food Safety & Nutrition	1428	1369	59	1321	48	38.6
CEPS	2	1	1	-	1	0.1
Ghana Health Service	25	25	-	24	1	0.7
Central Medical Stores	27	27	-	17	10	0.7
Police CID	6	6	-	3	3	0.2
Sierra Leone Pharmacy Board	40	37	3	34	3	1.1
Port Offices	149	140	9	128	12	4.0
Zonal Offices	4	4	-	-	4	0.1
Consumer Complaints	6	6	-	3	3	0.2
Request	44	44	-	36	8	1.2
Resubmission	48	48	-	41	7	1.3
Palm Oil	129	123	6	106	17	3.5
Total	**3,696**	**3,344**	**352**	**3,153**	**191**	**100.0**

5.1.1 Sample Analysis

Out of the total samples of 3696 received, 3,153 samples (85.3%) passed and 191 samples (5.2%) failed the analytical tests. 352 samples, representing 9.5% were not analyzed due to lack of equipment or full compliment of reagents and reference standards. Fig. 8 shows the status of sample analysis.

During the year, 168 samples of sachet water in the food category were analysed. Out of this number, 78 passed and 90 failed the analytical test.

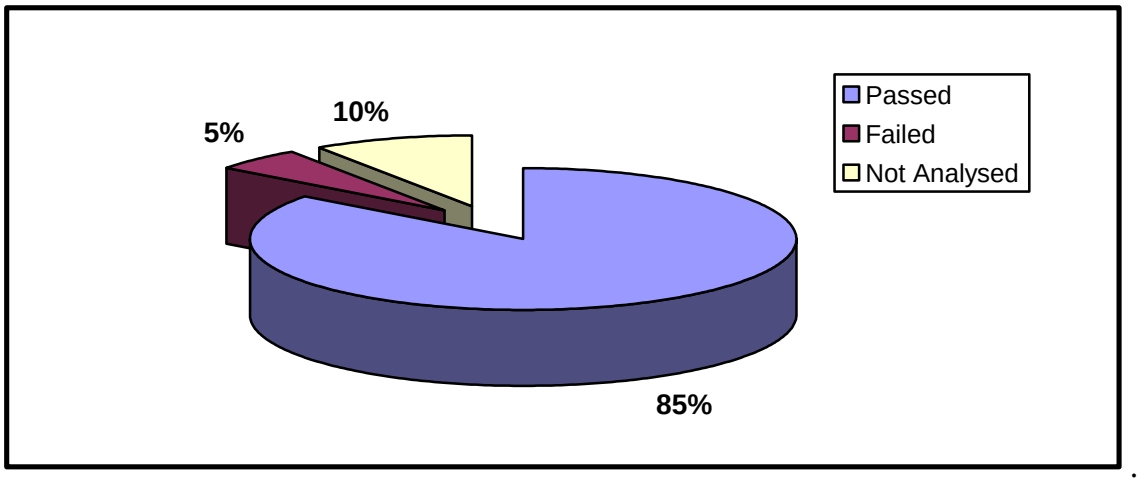


Fig. 8: Status of samples received

5.1.2 Palm Oil Screening

Following the European Union's insistence on the screening of palm oil exported from Ghana due to adulteration of potential carcinogenic compound of Sudan (I – IV) red dye, the Ministry of Trade, Industry and Presidential Special Initiatives mandated the Food and Drugs Board to come out with a guideline to regulate the exportation of palm oil.

From November to December 2004, 129 samples of palm oil were screened for the adulterant. Out of this number, 106 samples (82%) were found not to contain the adulterant while 23 comprising 18% were contaminated with Sudan IV dye

5.1.3 Equipment

In order to increase the analytical capacity of the Laboratory, high precision instruments were acquired and installed during the year under review. The instruments installed included a High-Head six-station Dissolution tester donated by United States Pharmacopoeia Commission with sponsorship from the United States Agency for International Development (USAID) through Management Sciences for Health (MSH). A

Gas Chromatograph (GC) and Atomic Absorption Spectrometer (AAS) were installed, which are now fully functional.

5.1.4 Other Analytical Functions

During the year under review, the Quality Laboratory offered analytical services to the Ghana Health Services under a project to assess the quality of anti-malarial on the Ghanaian market. The laboratory undertook a similar project for Management Sciences for Health through Central Medical Stores.

The Quality Laboratory also participated in collaborative trials under the auspices of the World Health Organisation (WHO). The first trials involved the use of ultraviolet spectrophotometer. The subsequent trials will be done in 2005, which will involve the use of HPLC and titration.

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, non-alcoholic 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.

During the period under review, 740 samples were received. Out of this number, 708 samples were analysed. 515 samples passed the microbiological test and 195 failed. Tables 12 and 13 show the sample source and the status of the samples analysed during the year under review, respectively.

Table 12: Sample Source

Sample Source	Water	Food	Drugs	Herbal	Total
Inspectorate/PMS	82	1	-	4	87
Food Safety & Nutrition	168	339	-	-	507
Drug Evaluation & Reg.	-	-	-	111	111
Pharmacy Board, Sierra Leone	5	-	27	-	32
Criminal Investigation Dept.	-	-	-	3	3
TOTAL	**255**	**340**	**27**	**118**	**740**

Table 13: Sample Status

Sample Category	Total Received	Analysed	Passed	Failed	Not Analysed
Water	255	255	139	116	-
Food	340	328	310	18	12
Drugs	27	7	7	-	20
Herbal	118	118	62	56	-
TOTAL	**740**	**708**	**515**	**193**	**32**

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

From June – December 2004, a baseline study was conducted for the various brands of condoms on the Ghanaian market to ascertain their quality and its conformance to the ISO 4074. In all 47 samples comprising 24 different brands of condoms were analysed. Out of this number, 34 samples passed the condom test. Table 14 indicates the results of condoms analysed.

The Unit also developed guidelines for the importation, testing and handling of condoms in Ghana, during the same period under review.

Table 14: Status of Condoms Analysed

Source	Total Received	Analysed	Passed	Failed	Not Analysed
Importers – Baseline Determination	34	29	22	7	5
Registration	13	13	12	1	-
TOTAL	**47**	**42**	**34**	**8**	**5**

PORT OPERATIONS

In 2004, the Board had two operational port offices located at Kotoka International Airport (KIA) and Tema Sea Port.

The principal function of these offices is to conduct destination inspection of imported products that fall within the purview of the Food and Drugs Law, PNDCL 305 (B). The inspection covers the expiry dates, manufacturing dates, batch/lot numbers, packaging, storage, physical condition of the goods, quantities, number of different items imported, the registration status of the products amongst others. A report on the inspection is issued to the Head Office which issues permits through the port offices to the importer for the goods to be released.

During the year under review, 2,405 import permits were received by the Tema Port Office covering the following categories of importers:

Food: 38

Drug:	72
Cosmetics:	16
Medical Devices:	11
Household Chemical Substance:	28
Total	**165**

During the year, an amount of ¢852,230,000.00 and $1,400.00 respectively were realised as destination inspection fees by the Tema Port Office whilst KIA Office generated ¢17,000,000.00. Table 15a and 15b indicate the summaries of permits received for the various categories of products in 2004 by Tema and KIA Office, respectively.

Table 15a: Summary of Permits Received at Tema Port in 2004

Month	Finished Product	Raw Materials	Total
January	91	69	160
February	91	65	156
March	120	102	222
April	122	66	188
May	88	58	146
June	107	88	195
July	133	92	225
August	134	85	219
September	141	104	245
October	113	90	203
November	135	78	213
December	142	91	233
Total	**1,417**	**988**	**2,405**

Table 15b: Summary of Permits Received at KIA Port Office in 2004

Month	Permits Received	Permits Cleared
January	96	46
February	59	53
March	75	69
April	52	50
May	85	84
June	67	67
July	76	68
August	64	63
September	78	75

October	91	87
November	63	60
December	57	56
Total	**863**	**778**

The revenue generated by the two Port Offices during the year under review is shown in Fig. 9.

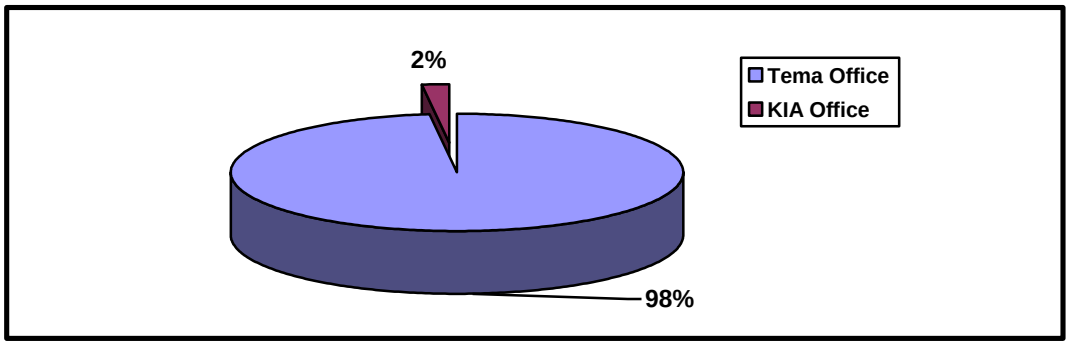


Fig. 9: Revenue Generated by the Port Offices

ZONAL OPERATIONS

Before 2003, the Board had only one Zonal/Regional Office located at Kumasi to carry out its mandate in Brong Ahafo and Ashanti regions. In 2003, the Takoradi and Bolgatanga Zonal Offices were opened, respectively. In 2004, one Zonal Office was added to augment the number to four. The Zonal Offices are:

- Bolgatanga Zonal Office, responsible for Northern, Upper East and Upper West regions.
- Kumasi Zonal Office, responsible for Ashanti and Brong Ahafo 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:

- Monitoring of advertisements on the electronic media

- Embark on consumer awareness programmes such as radio talk shows, seminars, lectures, and press release etc.
- Organised stakeholders meeting
- Inspections including post-market surveillance
- Consumer complaints protocol to deal with consumer issues
- Sale and processing of application/permit for premises, product registration and renewals
- Registration of importers of food, drugs, cosmetics, household chemicals, and medical devices.

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.

7.1 Zonal Activities Conducted in 2004.

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 was 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. Table 16 shows the summary of activities performed by the various Zonal Offices.

Table 16: Summary of Activities by Zonal Offices

Activity	Bolgatanga Zonal Office	Kumasi Zonal Office	Takoradi Zonal Office	Ho Zonal Office
Pre-licensing Inspection	21	85	298	35
GMP/Audit Inspections	44	93	-	-

Follow-up Inspections	-	61	656	-
Destination Inspections	-	5	18	3
Warehouse Inspections	-	13	6	-
PMS Activities	4	18	214	38
Seizures				
▪ **Food (Assorted)**	92	-	-	20
▪ **Drugs (Assorted)**	72	-	-	18
Meetings with Stakeholders	2	-	-	-
Seminar/workshop	Nil	12	6	1
Consumer Complaints	Nil	19	-	6
Media Interview and Programmes	-	-	-	6
Product Advert Monitoring (frequency)	Nil	3	-	-
Total Amount Generated	¢26,640,000.00	¢219,280,000.00 $2,000.00	¢82,710.000.00 $500.00	¢16,410,000.00

Figure 10 shows the comparative Zonal Offices' total revenue collected in 2003 and 2004.

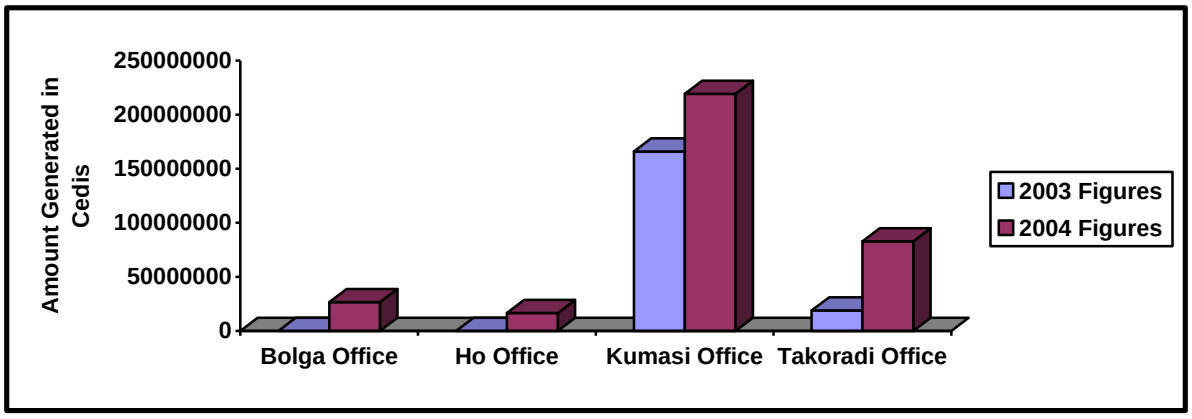


Fig.10: Comparison of Total Amount Generated in Cedis for 2003 and 2004.

7.1.1 Border Posts

During the year, the Board acquired an office accommodation at Elubo, a border town on the western frontier between Ghana and La Cote D'Ivoire to serve as a Border Post for official commissioning in 2005. Other surveys have been carried out in the Upper East region, namely Kulungugu, Misiga, Pulmakom and Paga in a bid to opening additional Border Post.

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 Board's strategic direction for 2005 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.
- To become ISO 9001: 2000 Quality Management System compliant.
- To install efficient information technology monitoring system to capture and generate important data by December 2005.

FOOD AND DRUGS BOARD MANAGEMENT TEAM

Chief Executive	Mr. E. K Agyarko
Dep. Chief Executive	Mr. Ben K. Botwe
Head, Drug Division	Mr. Ben K. Botwe
Head, Food Division	Mr. Kwamina Van-Ess
Head, Quality Control Laboratory	Rev. J. Y. Martey
Head, Finance & Administration	Rev. J. Y Martey (Acting)
Board Secretary	Mrs. Yvonne Nkrumah

Head Office:

Food and Drugs Board

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E-mail: fdb@fdbghana.gov.gh

Regional/Zonal Offices:

Kumasi Zonal Office (Responsible for Ashanti and Brong Ahafo regions)
Address: The Zonal Officer
Food and Drugs Board
P O Box ST 402, Kumasi, Ghana.
Location: SIC Building 2nd Floor, Bompata, Kumasi
Tel: 051-36070
Fax: 051-36070

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

Bolgatanga Zonal Office (Responsible for Northern, Upper East and Upper West regions)
Address: The Zonal Officer
Food and Drugs Board
P O Box 612, Bolgatanga, Ghana.
Location: Regional Administration Building
Tel: 072-23727
Fax: 072-24590

Ho Zonal Office (Responsible for Eastern and Volta regions)
Address: The Zonal Officer
Food and Drugs Board
PMB, Ho
Ghana
Location: Ghana News Agency Building
Tel: 091-65529
Fax: 091-28411