REPUBLIC OF GHANA

2005
ANNUAL REPORT

FOOD AND DRUGS BOARD

National Agency Responsible for the Regulation of Food and Drugs

.....Working for your safety

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1.0 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

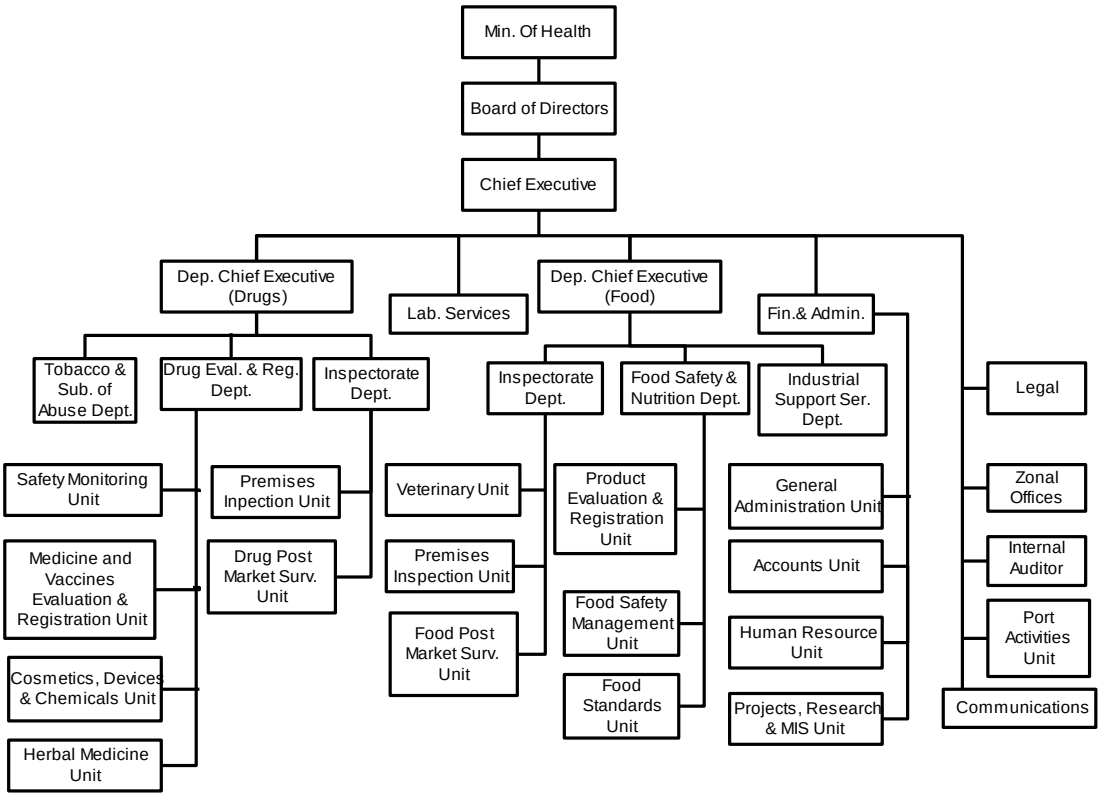
The Food and Drugs Law, 1992 (PNDCL 305B) and Food and Drugs Amendment Act 523, 1996 provide for a management structure spear-headed by a Governing Board appointed by the President of the Republic of Ghana.

The Governing Board of Food and Drugs 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, Professor in Pharmacology KNUST, Kumasi, University of Malaysia and UGMS.
Mr. E. K. Agyarko	Chief Executive, Food and Drugs Board.
Mr. John Pwamang	Environmental Protect Agency.
Mr. Joseph Nyoagbe	Ag. 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. Adu Gyamfi Darkwa	Executive Director, Ghana Standards Board.
Dr. Francis Ofei	Ghana Medical Association.
Ms. Felicia Otchere-Darko	Attorney General's Department.
Prof. Anna Lartey	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	Representing Traditional Medicine Practitioners.

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 2005.

2.0 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 2005 saw the continuation of capacity building in human resource base, with the staff strength increased from 130 to 175. The Board trained two nationals of Niger in Quality Assessment of Condoms and Medical gloves. The Board continued to offer laboratory testing services in support of the Pharmacy Board of Sierra Leone. The European Union team on palm oil control audited the Board's quality management system for the pre-export control of palm oil. According to the team, the Board's quality management system for palm oil is excellent.

The period also saw the Board using new guidelines to enhance regulatory functions after the Governing Board had given approval to review the old guidelines. The Board instituted a programme to implement ISO 9001:2000 and ISO 17025 certification system, respectively.

2.1.1 Human Resource Analysis

As at 31st December 2005, the total staff strength of the Food and Drugs Board stood at 175. The breakdown is as follows:

Total Male staff: - 118

Total Female staff: - 57

Total Senior Staff: - 124

Total Junior Staff: - 51

Age Distribution

- 20 – 35 - 87
- 36 – 45 - 64
- 46 – 55 - 22
- 56 and < 60 - 2

Staff on Contract - Nil

As at 31st December 2005, the following staff members have resigned or vacated their post:

No. of Resignations

Total Male Staff; - 4

Total Female Staff: - 3

Vacation of Post/Dismissal

Total Male Staff: - 2

Total Female Staff: - Nil

2.1.2 Resource Analysis

2.1.2.1 Infrastructural

The Board currently rents all its operational offices - the Head Office and the Zonal Offices. The summary of infrastructural analysis is given below:

Location	Number of Office Accommodation
Head Office - Accra	1
Technical Wing – Accra	1
Laboratory – Accra	1
Port Offices – Accra/Tema	2
Bolga Office	1
Ho Office	1
Kumasi Office	1

Takoradi Office	1
Elubo Office	1
Total	**10**

During the period under review, the construction of a new Head Office and Laboratory Building Complex started. It is expected that the building complex will be completed by the end of December 2006.

2.1.2.2 Transport

The Board has 41 vehicles including 11 saloon cars. In addition, the Board has 5 motorbikes. The summary of vehicle analysis is given below:

Official vehicle (Strategic Managers/Heads of Department – 7 Octavia and 4 – Toyota Saloon cars)	- 11
Operational Vehicles (27 – Pickups and 3 – Buses)	- 30
Motorbikes	- 5

2.1.2.3 Information Technology Equipment

The total number of Food and Drugs Board information technology equipment as at 31st December 2005 is given below:

Desktop Computers	- 97
Uninterruptible Power Supply	- 90
Laser Printers	- 47
Notebook Computers	- 10
Photocopiers	- 9
Manual Typewriters	- 4

2.1.3 Human Resource Development

To enhance the skills of the staff through short, medium and long term training courses, two staff benefited a 6-week course in Food Technology in Israel. The Board secured Ministry of Health Fellowship for one staff to pursue postgraduate degree in Medicine Control in the UK. Additionally, other staff members attended various courses, and training in the field of medicine and food regulation.

The summaries of courses attended by staff during the period under review are as follows:

- Two staff attended a short course in Food Safety and Bio-technology in China.
- One staff attended a 5-month course in Pharmacovigilance and Pharmaco-epidemiology at the London School of Hygiene.
- Two staff attended a course in Vaccine Safety in South Africa.
- One staff attended a course on Management of Condom Supply in Sweden.
- Six officers attended various Codex Committee meetings in Argentina, Australia, Germany, Italy, Holland and the USA.
- One staff attended laboratory training in Strasbourg, France.
- One staff attended a course in Clinical Trials in the UK.
- One staff attended a workshop on Medicine Regulation in Vienna.
- Two staff were on Industrial attachment at India Multinational company for four weeks.

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.

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.

2.3.1 Food and Drugs Bill

In the year under review, a meeting was held with Management and heads of Departments to discuss the first draft of the Food and Drugs Bill with Justice Crabbe, the Statute Law Review Commissioner. Comments and interventions have since been submitted to Justice Crabbe to be incorporated into the Draft Bill.

2.3.2 Tobacco Control Bill

A meeting with the tobacco industry was organised by the Board to discuss the Draft Tobacco Bill. Comments from the industry have been incorporated to the extend that it does not conflict with the provisions of the Framework Convention on Tobacco Control. A memorandum of accompanying the Bill, which seeks to justify the need for tobacco control, has been forwarded to the Minister of Health for final Cabinet approval to enable the Minister lay it before the Parliament.

2.3.3 Amendment of PNDCL 305B

Approved amendment of PNDCL 305B to allow for the Food Site Verification Programme and give the Board the mandate to charge fees and retain some for the

running of the office has been laid before Parliament. The 1992 Constitution of the Fourth Republic provides that charging and retention of fees should be approved by parliament.

The proposed Bill has been drafted with the accompanying memorandum justifying the amendment for the Board to carry out foreign inspections and charge fees. Cabinet has granted the necessary policy approval for the amendment.

The Fee Schedule has been submitted to the Attorney General's Office and the necessary regulations are yet to be drafted by the Attorney General's Office.

2.3.4 Regulation of Fortification of Wheat Flours and Vegetable Oils and Advertisement of Alcoholic Beverages.

In 2005, one Draft Regulation on fortification of wheat flours and vegetable oils and one draft regulation for the advertising of alcoholic beverages were submitted to the Minister of Health for Cabinet approval.

2.3.5 Court Cases

During the year under review, the Board attended to two court cases. A Member of Parliament filed a writ in the Supreme Court challenging the Board's authority to charges fees. The Legal mandate to charge fees has been raised in relation to the Food Site Verification Programme. The matter has since been withdrawn following discussions, which led to the amendment of the Law.

In another instance, Far East Mercantile Limited challenged the mandate of the Board to demand administrative charges and regulate advertisement of drugs and food. The action was in respect of the underlisted products.

- Odomos Mosquito Repellent
- Mentos

The Board has since filed a defence to the case. Subsequently, the company has meet with Officials of the Board to amicably settle the matter.

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 in Table 1.

Table 1: Summaries of Activities conducted by Communications in 2005

Area of Activity	**Frequency**	**%**
Press Release	29	34.9
Media Coverage	21	25.3
Media Interviews and Programmes	33	39.8
Total	**83**	**100.0**

The Unit also coordinated travels for Officers going for trainings, inspections, meetings and conferences overseas. The total travels within the year under review, was forty five (45).

3.0 DRUGS DIVISION

The Drugs 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 carried 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.

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 issue 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, 903 applications were received and 920 were registered including applications brought forward from December 2004. Additionally, 144 applications for medicine importers were received, whilst only 43 were registered.

Table 2 gives the summary of the breakdown of applications processed and registered by the Unit in 2005.

Table 2: Breakdown of Applications Processed and Registered

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Allopathic (orthodox) Drugs	636	155	608	204*
Veterinary Drugs	38	4	55*	4
Food Supplements	68	2	48	1
Vaccines	-	-	-	-
Total	**742**	**161**	**711**	**209**

*Contains processed applications brought forward from December 2004 and approved in 2005

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 2005, the Unit vetted 294 advertisement applications in various categories and approved 123. Table 3 gives the summary of advertisements processed in 2005.

Table 3: Advertisements Received and Processed in 2005

Area of Advert	No. of Applications	Number Approved
Print media	27	12
Radio	158	63
Television	98	37
Promotional materials	11	11
Total	**294**	**123**

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.
- Ensuring that 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 2,968 import permits covering the following products: finished products, pharmaceutical raw materials, hospital supplies, donations and prescriptions for personal use.

Table 4 shows the summary of import permits processed from January to December 2005.

Table 4: Summary of Import Permits Processed in 2005

Permit Category	Total Number Processed
Finished Products	2,173
Raw Materials	779
Hospital Supplies	-
Donations	16
Personal Use	-
Total	**2,968**

3.1.2 Safety Monitoring Unit

The functions of Safety Monitoring Unit are:

- 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, the National Pharmacovigilance Centre was re-designated from the Centre for Tropical Clinical Pharmacology and Therapeutics to the Food and Drugs Board, which was signed by the Minster of Health. The year also saw the inauguration of 11–member Technical Advisory Committee for Pharmacovigilance functions. The summaries of activities conducted in 2005 are shown in Table 5.

Table 5: Summary of Safety Monitoring Activities conducted in 2005

Activity Type	
Suspected Adverse Drug Reports Received	100
Number of reaction to Insecticide Treated Net reports received	2
Number of Adverse Events Following Immunisation (AEFI) reports received	7
SAVVY Clinical Trials	11
Virtual Access Trials	4
Alerts received	4
Institutional Contact Person Training: Northern Sector: Southern Sector:	 21 27
Zonal Desk Officers Training: Northern Zone: Southern Zone:	 2 3
Training on AEFI (Greater Accra)	31
External Training in ARFI surveillance	2
Number of draft concept for suspected Adverse Drug Reaction Posters for Public Education	7

The Management of the Board has given approval for a research to be conducted on adverse reaction associated with Insecticide Treated Nets use in Ghana. A consultant has been contacted and funds are being sought for the research to start.

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, 141 foreign and 166 local herbal products were evaluated. Out of these, 99 foreign and 75 local herbal products were registered, respectively. This is shown in Table 6.

Table 6: Summary of herbal products received and registered in 2005

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Herbal Drugs	141	166	99	75
Total	**141**	**166**	**99**	**75**

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 7 shows the number of products received and registered during the year under review.

Table 7: Summary of cosmetics, household chemical substances and medical devices products received and registered in 2005

Product Type	**Applications Received**		**Number Registered**	
	Foreign	Local	Foreign	Local
Cosmetics	568	54	430	29
Household Chemicals	59	11	32	10
Medical Devices	215	4	90	4
Total	**842**	**69**	**552**	**43**

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
- Operational Research Unit

The Department's main activities include 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).

During the year under review, the Tobacco and Substance of Abuse took full responsibility of the narcotic drugs and psychotropic substances functions, which used to be part of Drug Post-Market Surveillance Unit. Similarly, in 2005, operational research, monitoring of advertisements and promotion of collaborative activities were assigned to a newly formed Unit within the Department called Operations Research Unit.

3.2.1 Premises Inspection Unit

The principal functions of Drug Premises Inspection Unit are:

- Conducting pre-licensing and routine audit inspections of all the pharmaceutical manufacturing companies 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.

3.2.1.1 Inspection of Local Pharmaceutical Manufacturing Companies

In 2005, the Unit conducted 53 routine inspections and 42 pre-licensing inspections in pharmaceutical manufacturing plants. Table 8 shows the summary of routine and pre-licensing inspections conducted in 2005

Table 8: Summary of types of inspections conducted in 2005

Type of Manufacturing Plant	**Routine Audit Inspections Conducted in Manufacturing Plants**	**Pre-licensing Inspections Conducted**		
		Total No. Inspected	**No. Approved**	**No. Pending Approval**
Allopathic Medicines	18	9	2	7
Herbal Medicines	27	33	7	24
Cosmetics	7	0	0	0
Household Chemical Substances	1	1	1	1
Medical Devices	0	0	0	0
Total	**53**	**42**	**10**	**32**

3.2.1.2 Inspection of Foreign Pharmaceutical Companies

Overseas Good Manufacturing Practice (GMP) audit inspections of pharmaceutical companies carrying out business in Ghana were carried out during the period under review.

In 2005, 18 foreign pharmaceutical manufacturing facilities were inspected, out of which 17 were found to be Good Manufacturing Practice (GMP) compliant, while 1 company was found to be GMP non-compliant.

3.2.1.3 Inspections of Local Cosmetic and Household Chemicals Manufacturing Industries

A total of 7 cosmetics manufacturing companies were visited to sensitise them on the need to subject their companies for regulation.

3.2.1.4 Special Inspections

The Unit conducted 8 special inspections for various reasons out of which 2 were foreign, during the year under review. The special inspection was necessitated by the survey conducted on the open market, which revealed that Nouvelle Perfumeries Grandeur and Sivop Products contain units of Hydroquinone and steroids, which were above recommended limits. This revelation led to special inspections to the manufacturing facilities of the affected products.

The presence of Hydroquinone and steroids were established out of the investigations conducted. The appropriate regulatory sanctions have instituted against the companies.

3.2.1.5 Inspection to ascertain HPLC Acquisition

In order to ensure local pharmaceutical manufacturing industries produce quality, safe and efficacious products, the Board in the year under review requested that local pharmaceutical industries to acquire HPLC. This was to ensure that their respective Quality Control Laboratories perform relevant tests.

Out of 22 companies that were inspected, only 4 had acquired the HPLC.

3.2.2 Drug Post-Market Surveillance Unit

The Unit monitors medicines, cosmetics, medical devices and household chemicals to ensure 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 the 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 pharmaceutical counterfeiting.

3.2.2.1 Inspection of Pharmaceutical Warehouse

In 2005, 38 pharmaceutical warehouses were inspected. The purpose of the inspection was to find out the level of compliance of importers and wholesalers of pharmaceutical products to current code of Good Storage Practices and Good Warehouse Practices since these affects the product quality. It was observed that almost all the companies do not conduct temperature monitoring of the storage facility to ensure that they conform to the storage condition recommended by the manufacturer.

3.2.2.2 Supervision of Safe Disposal of expired Pharmaceutical Products

The Unit supervised the safe disposal of unwholesome pharmaceutical and related products from 20 Pharmaceutical Companies. This was done in collaboration with the Accra Assembly who owns the Waste Damping Site.

3.2.2.3 Consumer Complaints

The Unit conducted investigations into various complaints that were brought to the attention of the Board by individuals and corporate bodies. In 2005, out of 30 complaints, 27 were fully addressed.

3.2.3 Drug Operational Research Unit

The Operational Research Unit of the Drug Inspectorate Department was formed out of Drug Post-Market Surveillance Unit in July 2005 to take care of advert monitoring, promotion of collaborative activities, operational research and coordination of all training programmes of the Drug Division.

From July – December 2005, the following programmes were undertaken:

3.2.3.1 Research, Projects and Sampling

The Unit started a research project of conducting assessment of Ciprofloxacin tablets on the market. The study was to serve as a pre-test to a major nationwide study to assess the level of counterfeit and substandard drugs on the Ghanaian market. It is expected that scale-up study shall serve as a scientific health enquiry into fake drugs (epidemiology of counterfeit drugs) providing valid scientific data on the presence and extent of counterfeit and substandard drugs on the market.

Up to December 2005, the following tasks have been accomplished:

- Purchase of Ciprofloxacin tablets
- Verification of the registration status of the products
- Evaluation of product insert

The samples have since been sent to the Quality Control Laboratory for analysis.

3.2.3.2 Inventory of Monotherapies of Antimalarial on the Market

As part of activities that will lead to the full implementation of the new malaria treatment policy of using Artesunate combination therapy as the first line of treatment of malaria, an exercise was conducted by the Unit from 7th – 21st September 2006.

The exercise was aimed at establishing approximate quantities of the Monotherapies on the market, the quantities of raw and finished products in the warehouses of local pharmaceutical industries as well as Central and Regional Medical Stores. The exercise has been completed and the report submitted to Strategic Management.

3.2.3.3 Advertisement Monitoring

The Unit monitored 219 unregistered advertisements from July – December 2005. The details are shown in Table 9.

Table 9: Summary of unauthorised advertisements monitored in 2005

Period	**Allopathic Drugs**	**Herbal Products**	**Cosmetics**	**Medical Devices**	**Total**
Jan – March 2005	14	3	1	-	18
August 2005	46	31	15	11	103
September 2005	49	31	10	8	98
Total	**109**	**65**	**26**	**19**	**219**

The regulatory action taken against the affected companies was the issuing of disclaimers in the print media. The appearance of the disclaimers made some of the companies to submit their adverts for vetting by the Board.

3.2.3.4 Training

The Unit coordinated 3 training workshops/seminars organised by the Drugs Division from July – December 2005. The details were as follows:

- Training workshop on Good Formulation Practices for local pharmaceutical manufacturing industry
- Seminar for manufacturers of extemporaneous preparations
- Training workshop for warehouse managers/supervisors on Good Storage Practices

3.3 Tobacco and Substance of Abuse Department

The Department was established in January 2005 to control tobacco and tobacco products, licit narcotic drugs, psychotropic substances and precursors in Ghana.

The Department has a goal to reduce the mortality and morbidity caused by the use of tobacco products and to have good administration on narcotic drugs, psychotropic substances and precursors. The Department started operation in the second quarter of 2005, after two additional staff members had been posted to the Department.

3.3.1 Control of Tobacco

No activity in relation to tobacco control was undertaken during the period since the Bill on Tobacco has not yet been passed by parliament. However, 2 proposals had been submitted to donor organisations for funding, which are receiving attention. These included a proposal for the formation of no smoking clubs in 50 selected second cycle schools in the country and training of community-based Pharmacists to give support for smokers who want to quit the habit of smoking in their communities.

3.3.2 Control of Psychotropic Substances

During the course of the year, 61 import permits were granted. The Department received 19 Advice of Receipts for permits granted. 14 companies submitted Returns on Products they imported. Out of 26 Export Authorisation Forms received from exporting companies for endorsement, only 3 were endorsed.

3.3.3 Other Activities performed by the Department

The Department participated in the celebration of World No Tobacco Day. All outstanding returns to the International Narcotics control Board (INCB) were prepared and sent to the INCB. Out of 6 Multilateral Chemical Reporting Notifications received from South Africa, the Department objected to the shipment of 4 of them since investigations conducted by the Department revealed that the supposed importers did not authorize and had no knowledge of the shipments.

4.0 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 for food safety and quality. This is carried out by evaluating all samples submitted for registration.

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

The activities of the Division are carried out by 3 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:

i. Advising on the safety and quality of food products
ii. Conducting evaluation meetings for food product approval.

iii. Evaluating food product labels to ensure conformance to the labelling law.

iv. Registering food products.

In 2005, a total number of 668 food products were submitted to the Board for registration. Out of this number, 153 representing 22.9% were locally manufactured whilst 515 representing 77.1% were imported products. Table 10 below illustrates the summary of food products submitted and registered by the Unit.

Table 10: Summary of Food products submitted and registered in 2005

Product Category	**Total No. of Imported Products Received**	**Total No. of Imported Registered Products**	**Total No. of Locally Manufactured Products Received**	**Total No. of Locally Registered Products**
Drinks	161	141	43	147*
Fats and Oils	59	35	4	4
Confectionery	126	58	5	1
Packaged Water	3	2	66	67*
Fish/ Fish Products	9	13*	2	2
Diary and Diary Products	25	23	4	6*
Additives	33	24	12	13*
Meat and Meat Products	14	9	2	0
Roots and Tubers	2	2	-	4*
Fruits	1	0	1	0
Cereals	50	30	8	3
Vegetables	28	29*	6	9*
Pet Food	4	4	-	-
Total	**515**	**370**	**153**	**256**

*Contains processed products brought forward from December 2004 and approved in 2005

During the year under review, 266 food products were deferred for one or more of the following reasons:

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

4.1.2 Food Standards Unit

The Unit was set to make available the appropriate food standards and develop 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 130 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. Seven 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 2005, 14 Guidelines were reviewed and 12 food application forms were updated to meet current requirements.

4.1.3 Food Safety Management Unit

The Food Safety Management Unit (FSMU) is 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 2005, the Unit successfully organised the third National Food Safety Week in Takoradi as part of the food safety awareness creation campaign from 20th – 26th June 2005. The Unit was also involved in food safety audits involving five Food Processing Companies, namely:

- Accra and Kumasi plants of the Coca Cola Bottling Company of Ghana Limited (CCBGL),
- Home Foods Processing and Cannery Limited
- MacBells Company Limited
- Silver Springs Company Limited
- Ghana International School Canteen

In addition to the above audit inspections, the Unit extended the exercise to 45 restaurants within the Accra Metropolis, which yielded good results.

4.1.3.1 Training Programmes and Workshops

The Unit organises training programmes as part of its work programme. This is conducted in collaboration with other Units, Departments and Institutions. In 2005, the Unit organised or was part of the following training programmes:

- One day training in the Principles and Application of HACCP for 20 SMEs.
- One training programme was organised for 50 street vendors in Accra-Tema Metropolis.
- A two-day GMP training programme for staff of Tata Beverages Limited
- A two-day GMP training programme for staff of Silver Springs Company Limited.
- In view of increasing incidence of imitation of locally manufactured liquor, the Unit organised a one-day seminar for importers of alcohol and manufacturers of

liquor to sensitise them on the need to provide adequate protection of products to discourage imitation and also to improve GMP status of their facilities.

- The Unit in collaboration with the Industrial Support Services Department, organised sensitisation workshop to educate local palm oil producers in the West Akim and Kwaebibirim Districts in the Eastern region.

4.1.3.2 Consumer Complaints

During the year, the Unit handled 7 consumer complaints. They involved food products such as:

Spices	-	1 complaint
Drinks and Beverages	-	3 complaints
Canned Product	-	1 complaint
Food served in Restaurant	-	3 complaints

All the complaints were investigated and solved and the reports duly submitted for action.

One common observation made during the investigations is that food safety management systems put in place were not adequate and could be the failures observed.

4.2 Food Inspectorate Department

The Food Inspectorate Department 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 warehouses to ensure Good Warehouse Practices (GWP).

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

4.2.1.1 Specific Activities Undertaken

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

- Organised a mapping out exercise in Accra-Tema Metropolis to locate cold stores, meat shops, supermarket (with butcheries) and feed mills. In all 142 facilities were located. The details are as follows:
    - Cold Stores - 75
    - Meat Shops - 39
    - Supermarkets (with butcheries) - 12
    - Feed Mills - 16
- Organised routine, follow-up and emergency inspections to meat shops, cold stores and supermarkets to ensure Good Hygienic Practices. The summary of facilities inspected are as follows:

Facility Type	Routine	Follow-up	Emergency
Meat Shop	36	3	-
Cold Store	43	8	4
Supermarket	7	2	1
Total	**86**	**13**	**5**

- The Unit organised a sensitisation workshop for Butchers and Environmental Health Officers drawn from Northern, Upper East and Upper West regions. This was to ensure national campaign on safe handling of meat and meat products. In all 111 Environmental Health Officers and 98 Butchers attended the workshop.
- A one-day workshop was organised for cold store, meat shops and supermarket supervisors in Accra-Tema Metropolis on regulation of meat handling.

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 the registration of products manufactured in-plant.
- Routine inspection of food manufacturing premises to ensure current Good Manufacturing Practices (cGMP).

During the year under review, 104 manufacturing companies were visited and inspected. Table 11 shows the manufacturers and the categories of the food products.

Table 11: Manufacturers and the various food categorisations

Food Category	Manufacturers	%
Water	60	57.7
Diary Products	4	3.8
Vegetables	3	2.9
Drinks (Non-Alcoholic)	14	13.5
Drinks (Alcoholic)	12	11.5

Confectionery	4	3.8
Additives	5	4.8
Fruit	Nil	-
Catering	Nil	-
Fish and Fish Products	Nil	-
Fats and Oils	2	2.0
Cereals	Nil	-
Root and Tubers	Nil	-
Meat and Meat Products	Nil	-
Total	**104**	**100**

Table 12 also shows the level of GMP compliance. Out of 104 manufacturers only 49 representing 47.1% were granted registration licences. The remaining has to comply with the GMP codes of operation.

Table 12: Level of Compliance to GMP

Grading system	Number of companies	Compliance level in %
Excellent	20	19.2
Good	29	27.9
Fair	53	51.0
Poor	2	1.9
Total	**104**	**100**

The Unit covered 150 inspections in 2005 in various categories of types of inspections. The following were the summaries of the type of inspections conducted.

- Pre-licence 76
- Follow-up 38
- Re-registration 6
- Routine 15
- Emergency 15

4.2.3 Food Post-Market Surveillance Unit

The Unit undertakes the following functions to execute the mandate 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
- Supervising the destruction of unwholesome food products
- Investigating consumer complaints and any other relevant query regarding food products
- Monitoring food product registration and quality status of food products on the Ghanaian market.

In 2005, the Unit inspected 181food storage facilities (warehouses). The details of types of warehouse general inspections are shown in Table 13.

Table 13: Types of Food storage inspections conducted in 2005

Month	**Type of Inspections conducted**				
	Pre-Registration	**Routine**	**Emergency**	**Follow-up**	**Total**
1st Quarter	35	5	-	18	**58**
2nd Quarter	35	-	2	19	**56**
3rd Quarter	36	2	-	6	**44**
4th Quarter	20	1	-	2	**23**
Total	**126**	**8**	**2**	**45**	**181**

4.2.3.1 Annual Warehouse Inspections in Accra-Tema Metropolis

The Unit organises 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 pre-packaged 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 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, poor ventilation and documentation. No expired products were observed in all the warehouses the team inspected.

4.2.3.2 Inspection of Retail Outlets (Supermarkets)

In 2005, the Unit inspected 60 retail outlets in Accra-Tema Metropolis. This number is small compared to the supermarkets in Accra- Metropolis. This shortfall was due to inadequate staff strength and shortage of vehicles.

4.2.3.3 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 products with the Food and Drugs Board. Although the Board has made this known publicly, many food importing and manufacturing companies still flout the 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 2005, 68 sachet water producing companies, 109 locally manufactured dry processed foods, and 118 locally manufactured moist processed foods were picked out of the open market with

the aim of bringing the activities of those companies that manufacture or import these food products into compliance.

4.2.3.4 Consumer Complaints

As part of its functions, the Unit investigated 45 consumer complaints during the year under review. Out of this number, 29 complaints were appropriately acknowledged and investigated, whilst the others were either trivial or the state of the samples did not aid full investigations.

4.2.3.5 Processing of Advertisement Applications

During the year under review, 58 advertisement applications were received. Out of this number of applications, 32 or 55.2% were approved. The applications that were not approved of were products that had not been registered or of those that the applicants were asked to make some amendments to the script.

4.2.3.6 Monitoring of Destruction of Unwholesome/Expired Food Products

The number of destructions monitored increased considerably in 2005 compared with 2004 figures. Thirty two (32) voluntary destructions were monitored as compared to 12 in 2004. The reasons for the food products destroyed ranged from unwholesomeness, and expired dates.

In 2005, the total cost of food products destroyed totalled ¢4,255,135,599.45.

4.2.3.7 Annual Pre-Christmas Supermarket Inspections

The Unit conducts annual pre-Christmas inspections in all the major supermarkets and warehouses since this occasion experiences large influx of different food products. The objectives of the exercise were:

- To verify conformance of the labelling of pre-packaged foods to the General Labelling Rules (L.I. 1541).
- To determine the physical condition of food products in storage and on sale and their expiry dates status.

In all, 106 warehouses and 102 supermarkets were inspected, respectively. 32% 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.

4.3 Industrial Support Services Department

The Industrial Support Services Department commenced operations in January 2005. Its function is to provide technical support to industry through training and implementation of food safety and quality management systems.

The Department provided training in Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP) to SMEs. It also conducted audits of food industries and facilitated the installation of HACCP in SMEs.

As part of its regulatory activities, the Department has monitored the safety and quality of palm oil. This, it has achieved by ensuring GMP at processing sites and pack houses and curbing the adulteration of the oil with Sudan Dyes and other colourants. The Department has also been responsible for the inspection and issuance of sanitary certificates for the export of agro produce.

For the effective implementation of the Amendment Act 523, the Department served as the focal point on the Universal Salt Iodization Programme for the Board. The Department is also the focal point on National Food Fortification Alliance (NFFA). In these two capacities therefore, the Department plays a key role to improve the nutritional status of the Ghanaian population.

The Department was also involved in the Street Food Coalition. The function of the Board on this programme was to maximise food safety knowledge of food vendors through food safety and hygiene training.

The summaries of activities achieved during the period under view are as follows:

4.3.1 Training Programmes and Workshops

To upgrade the knowledge and skills of Small and Medium Enterprises (SMEs) and other relevant stakeholders in Hazard Analysis and Critical Control Point (HACCP), Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), Good Warehouse Practice (GWP), and Good Audit Practice (GAP), the following training programmes were conducted:

- **Training in HACCP**
    - 22 personnel from 20 companies were trained in Principles of HACCP. The training was sponsored by UNIDO.
    - HACCP team and Management of Barry Callebant trained.
    - HACCP plan reviewed and implemented at Barry Callebant.
    - Installed HACCP in 5 SMEs.

- **Training in GMP and GHP**
    - Staff of Tata Beverages and Silver Springs Limited trained.
    - 181 persons representing 90 sachet water producing companies trained in the Greater Accra and Volta regions.
    - Audited 5 food processing industries to ascertain the level of compliance to Good Manufacturing Practices.

- **Training in Aflatoxin Management in Groundnuts**
    - Staff, Management and Suppliers of Ghana Groundnuts Limited (GGL), Techiman trained.

4.3.2 Regulation of the Safety and Quality of Palm Oil

To curb the adulteration of palm oil with Sudan dyes to facilitate export and for consumer protection, the following activities were undertaken:

- **Sensitisation of Stakeholders on adulteration of palm oil with Sudan Dyes**
    - One stakeholders' meeting was held to discuss implications of adulteration of palm oil in international trade and the way forward for palm oil exporters, palm oil processors, palm oil distributors and retailers, Ministry of Trade and Industries, Customs Excise and Preventive Service, Environmental Health Directorate of selected District Assemblies and the General public.
    - Eleven markets were visited to sensitise market women on the dangers of Sudan Dye adulteration of palm oil.
    - 32 SMEs and one large palm oil processor were sensitised.
    - Environmental Health Officers of the Kwaebiribrim and West Akim District Assemblies were trained to monitor palm oil adulteration.
    - Sensitisation programmes organised on Television and Radio for the General Public.

- **Management of Food Alerts**
    - Thirty three (33) food alerts received from the EU and investigated. None of the consignments issued permits by the FDB has been implicated in the alerts.

- **Sampling and Screening of all palm oil samples intended for export**
    - 334 consignments were analysed. Of this, Sudan dyes were detected in 24 samples representing 7.2%.

- **Audit by Food and Veterinary Office of the European Union**
    - The visit was to ascertain the country's capacity to regulate palm oil export in relation to adulteration with Sudan dyes and other dyes

4.3.3 Universal Salt Iodation Programme

The aim of the Universal Salt Iodation Programme was to achieve 90% household consumption of iodated salt by end of 2005. The following activities were conducted in 2005 under the programme.

- Fifteen meetings were organised by the National Salt Iodation Committee and as well as two sub-committee on the enforcement of the Amendment Act 523.
- Organised 2 sensitisation programmes on radio on permit of importation of non-iodated salt.
- Organised 10 sensitisation and commissioning workshops for Authorised Officers on the Enforcement of the Salt Iodation Law in the Central, Greater Accra and Volta regions.
- Handed over Iodine Test Kits and 120 samplers to the Police Service and CEPS to enable checks at designated check points.
- Issued 8 permits to transport non-iodated salt.
- Audited 31salt processing companies and cooperatives in Central, Greater Accra and Volta regions for compliance with salt Iodation.

4.3.4 Issuance of Sanitary Certificates for Export of Agro-Produce

To regulate export of wholesome agro-produce, 16 Health Certificates were issued for the export of garden eggs to Italy and one Certificated issued on Sudan dye status for the export of pepper to the United Kingdom, during the period under review.

4.3.5 Street Vended Foods Project

The objective of the project was to improve on food safety knowledge of street food vendors. The Department attended 8 coalition meetings and prepared 7 food safety

modules under the review period. In addition, the Department conducted 5 training sessions for different groups of vendors and one impact assessment training.

4.3.6 National Food Fortification Programme (NFFA)

The principal objective of the project is to improve nutritional status through fortification of flour and cooking oil. In 2005, the following activities were conducted:

- One advocacy meeting was organised to review the progress of the fortification programme.
- One open forum was held for bakers drawn from all regions of the country.
- Drafted Legislative Instrument to enforce fortification of wheat flour and vegetable oil.

The Ghana-GAIN Appraisal Mission visited FDB to review Monitoring and Evaluation component of programme and the NFFA Action Plan for implementation.

5.0 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 the 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 Services (CEPS), Central Medical Stores (CMS) of Ghana Health Services, and the Pharmacy Board of Sierra Leone.

During the year under review, 3295 samples were received. These were made up of allopathic drugs (43.1%), cosmetics (11.3%), food (47.9%), herbal drugs (11.6%) and veterinary drugs (1.4%). Table 14 gives the summary of product categories received for the various analytical tests.

Table 14: Summary of product categories received and analysed

Sample Category	Received	Analysed	Not Analysed	Passed	Failed
Allopathic Drugs	1,160	1,054	106	973	81
Herbal Drugs	343	343	-	298	49
Veterinary Drugs	40	40	-	40	-
Food	1,417	1,417	-	1,393	24
Cosmetics and Household Chemicals	335	316	19	302	14
Total	**3,295**	**3,170**	**125**	**3,006**	**164**

5.1.1 Sample Analysis

Out of the total samples of 3,295 received, 3,006 samples (94.8%) passed and 164 samples (5.2) failed the analytical tests. 125 samples, representing 3.8% were not analyzed due to lack of equipment or full compliment of reagents and reference standards.

5.1.2 Palm Oil Screening

In 2005, the Unit continued with the screening of palm oil for export for the adulteration of Sudan I –IV dyes. In all, 384 samples were screened, 315 (83.3%) samples were found to be free of the adulterants whilst the remaining 69 (16.7%) were adulterated 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 two Agilent 1100 series HPLC. The installed equipment are now fully functional.

5.1.4 Other Analytical Functions

During the year under review, the Unit conducted a survey on behalf of the Board with funding from Management Science for Health (MSH) on the quality of Artemisinin Combination Therapy (ACT) products, which have been registered and are on the Ghanaian market. The project has since been completed and the report submitted to the Strategic Management of the Board and the sponsors of the project.

5.2 Microbiology Unit

The Microbiological 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, yeast, mould, and coliform counts. 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, 916 samples were received. Out of this number, 909 samples were analysed. 784 samples passed the microbiological test and 125 failed. Tables 15 and 16 show the sample source and the status of the samples analysed during the year under review, respectively.

Table 15: Sample Source

Sample Source	Water	Food	Drugs	Herbal	Medical Devices	Total
Inspectorate/PMS	2	23	-	6	-	31
Food Safety & Nutrition	66	469	-	-		535
Drug Evaluation & Reg.	-	-	93	157	83	333
Pharmacy Board, Sierra Leone	-	-	7	1	-	8
Criminal Investigation Dept.	-	-	-	4		4
Port Offices	-	5	-	-	-	5
TOTAL	**68**	**497**	**100**	**168**	**83**	**740**

Table 16: 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 provides services in the form of quality evaluation of medical devices. In 2005, the Unit extended its services to include the following medical devices:

- Syringes and needles
- Sanitary pads
- Cotton Wool
- Crepe and gauze bandages
- Latex Gloves
- Plasters

- Latex condoms

In 2005, 225 samples comprising the above products were analysed. Out of this number, 216 passed the evaluation test. Table 17 indicates the results of products analysed.

Table 17: Status of Medical Devices Analysed

Source	Total Received	Analysed	Passed	Failed	Not Analysed
Batch – Batch Testing	85	85	82	3	-
Registration	140	137	134	3	3
TOTAL	**225**	**222**	**216**	**6**	**3**

6.0 PORT OPERATIONS

The Board operates 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, and 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, 2,721 import permits were received by the Tema Port and an amount of ¢1,575,560,000.00 and $5,400.00 were realised as destination inspection fees by the Tema Port Office. Table 18a and 18b indicate the summaries of permits received and cleared for the various categories of regulated products in 2005 by the Tema and KIA Office, respectively.

Table 18a: Summary of Permits Received at Tema Port in 2005

Month	Finished Product	Finished Product Cleared	Raw Materials	Raw Materials Cleared
January	104	69	52	38
February	118	86	35	41
March	127	86	64	57
April	135	76	83	59
May	138	81	110	72
June	126	85	89	60
July	142	86	79	62
August	153	92	66	48
September	164	108	85	57
October	154	81	97	51
November	204	62	115	24
December	151	73	130	44
Total	**1,716**	**985**	**1,005**	**637**

Table 18b: Summary of Permits Received at KIA Port Office in 2005

Month	Permits Received	Permits Cleared
January	87	56
February	138	58
March	141	105
April	138	118
May	132	85
June	154	109
July	146	101
August	172	126
September	152	106
October	132	93
November	174	123
December	148	86
Total		

6.1 Detentions and Non-compliances

In 2005, a total of 215 regulated products covering food and its related products and medicines were detained by the Tema Port Office. The major non-compliances that led to the detention were on improper labelling. In addition the following were also missing:

- No or incomplete manufacturer's address
- No production date
- No expiry date
- No batch identification
- Food colours especially for confectionery not declared.

Table 19 shows the number of detentions made in 2005 for Tema Port alone.

Table 19: Number of Detentions made by Tema Port Office for 2005

Month	Food products	Medicines	Total
January	17	2	19
February	11	-	11
March	13	-	13
April	8	2	10
May	6	1	7

June	9	1	10
July	4	1	5
August	20	5	25
September	27	4	31
October	35	6	41
November	16	2	18
December	25	-	25
Total	**191**	**24**	**215**

7.0 ZONAL OPERATIONS

Before 2003, the Board had only one Zonal/Regional Office in 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, another Zonal Office was opened. The four 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
- Embarking on consumer awareness programmes such as radio talk shows, seminars, lectures, and press release, etc.
- Organising 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 2005

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 20 shows the summary of activities performed by the various Zonal Offices.

Table 20: Summary of Activities conducted by Zonal Offices in 2005

Activity	Bolgatanga Zonal Office	Kumasi Zonal Office	Takoradi Zonal Office	Ho Zonal Office
Pre-licensing Inspection	9	73	86	73
GMP/Audit Inspections	150	6	Nil	nil
Follow-up Inspections	22	42	nil	46
Unannounced Inspections	nil	115	Nil	nil
Destination Inspections	nil	nil	41	21
Warehouse Inspections	20	7	nil	
PMS Activities Freq.	116	19	161	98
Seizures				
▪ **Food (Assorted)**	352	-	-	43
▪ **Drugs (Assorted)**	257	-	-	-

Meetings with Stakeholders	3	nil	nil	1
Seminar/workshop	nil	4	nil	1
Consumer Complaints Addresses	7	nil	nil	2
Media Interview and Programmes	30	14	25	14
Product Advert Monitoring (frequency)	nil	nil	nil	6
No. of Destructions of Expired Products	nil	1	nil	5
Total Amount Generated	47,030,000.00	264,800,000.00	163,990,000.00	43,930,000.00

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 posts.

8.0 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 2006 will focus on the following:

- The decentralization programme for Sunyani Office and Koforidua Office will be executed for effective implementation and enforcement of the regulatory laws in Brong Ahafo and Eastern regions, respectively.
- The review of the Tobacco Bill will be completed by June 2006.
- The human resource situation will be critically examined and recruit qualified staff by the end of December 2006. Staff motivation will also receive increased attention.
- Staff will receive adequate training and development by the end of December 2006.
- 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 by June 2006.
- The consumer awareness programmes will continue to ensure public health and safety and consumer confidence.
- To become ISO 9001: 2000 Quality Management System compliant by December 2006.
- To install efficient information technology monitoring system to capture and generate important data by December 2006.
- The electronic permit system administered by the Ghana Community Network System GCNet will be fully operational by September 2006.

FOOD AND DRUGS BOARD MANAGEMENT TEAM

Chief Executive	Mr. E. K Agyarko
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

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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