BUREAU PROFILE

of

BUREAU OF FOOD AND DRUGS

By: Cristina A. dela Cruz
Food-Drug Regulation Officer III

Historical Background

1963 –

- **Republic Act 3720 (Food, Drug and Cosmetic Act) was enacted by Congress**
- **To carry out the provisions of the law, the Food & Drug Administration (FDA) was created.**
- **By virtue of RA 3720, the Division of Food and Drug Testing and the Board of Inspection both of the Department of Health which were then involved in food and drug control work were abolished and its powers, functions and duties transferred to the new FDA.**

1982 –

- **By virtue of E.O. 851 the Department of Health was reorganized and the Food and Drug Administration was abolished.**

Historical Background : (cont.)

1982 – (cont.)

- **The Bureau of Food and Drugs (BFAD) was created.**
- **The functions of the Narcotic Drug Division of the FDA was transferred to the Dangerous Drugs Board.**
- **E.O. 851 was superseded by E.O. 119 s. 1987 which again reorganized the BFAD and mandated it to be a policy-formulating and sector monitoring arm of the Health Minister on matters containing to food, drugs, medical devices, traditional medicines, cosmetics, household products containing hazardous substances.**

Historical Background : (cont.)

1982 – (cont.)

- **The Bureau was also mandated to formulate rules and regulations and standards in accordance with RA3720 and to enforce these laws**

1986 –

- **Following the EDSA Revolution, a Task Force on pharmaceuticals was created to review the policies and regulations pertinent to the drug system.**
- **This was the first step taken towards the formulation of a comprehensive National Drug Policy (NDP). Consistent with NDP, a National Drug Policy Program (NDPP) was developed.**

Historical Background : (cont.)

1987 –

- **BFAD moved to its new site, its present site where it acquired new facilities including sophisticated analytical instruments and a modern experimental animal laboratory through a grant from Japan International Cooperation Agency (JICA), Government of Japan.**

- **It was on the occasion of the inauguration of this new facility that then President Corazon Aquino declared publicly the Philippine National Drug Policy together with its four pillars: Quality Assurance, Rational Use of Drugs, Self-Reliance and Tailored Procurement.**

Target Clients:

- **Industries of:**
  - **Food**
  - **Drugs**
  - **Medical Devices**
  - **Cosmetics**
  - **Household Hazardous Substances**

- **Other government institutions**

- **Consumers**

VISION

A world-class food, drug and cosmetic regulatory agency

MISSION

To guarantee safe, quality, efficacious and affordable products for public health protection in partnership with stakeholders and to sustain leadership in regulatory excellence

CORE VALUES:

- **EXCELLENCE – We set the highest standard of performance and deliver the best quality and professional service.**
- **INTEGRITY - We are honest, sincere and transparent.**
- **QUALITY - We commit ourselves to total quality.**
- **EFFICIENCY – We produce timely results and achieve the goals we set with the least resources and effort.**

CORE VALUES: (cont.)

- **COMMITMENT – We dedicate ourselves first of all to the service of the Filipino people.**
- **COURTESY - We treat ourselves and our clients with respect and dignity befitting all fellow human beings.**
- **TEAM WORK – We work together and cooperate with each other to achieve synergy.**
- **CREATIVITY – We develop new ways of looking at and doing things**

MANDATE

The Bureau of Food and Drugs was created under RA3720, as amended by EO175. It is a regulatory and development-oriented agency to pursue its mandate to ensure the safety, efficacy, quality and purity of foods, drugs, cosmetics, medical devices and household hazardous substances. It is further authorized to administer and enforce pertinent laws, rules and regulations.

GOALS

SHORT TERM:

- **To plan ahead of time service delivery**
- **To document current practices into SOPs/Guidelines**
- **To propose a system of awarding deserving staff**
- **To identify training needs of staff for career pathing**
- **To allocate funds for the maintenance of equipment**
- **To retool/upgrade skills of technical staff**

GOALS (cont. . .)

MEDIUM TERM:

- **To solicit support of external partners for resources specifically for funds and training**
- **To guarantee effective system of resource generation from external resources for public health protection**
- **To guarantee an effective human resource development program for quality health services**
- **To sustain availability of state-of-the-art technology**

GOALS (cont. . .)

LONG TERM:

- To sustain quality and timely delivery of regulatory services
- To sustain an effective leadership role for public health protection
- To guarantee safe, quality and efficacious products for public health protection

OBJECTIVES

- **Safeguard and promote public health by ensuring the safety, efficacy, purit and quality of products under its jurisdiction**
- **Protect consumers and the public from false, deceptive and misleading information and health claims**
- **Ensure the scientific accuracy and soundness of all product information conveyed to the public**
- **Guide and assist manufacturers, importers, distributors and retailers of products it regulates i.e. processed pre-packaged foods, drugs including vaccines and biological in vitro diagnostic reagents, medical devices, cosmetics and hazardous substances used in the household**

KEY RESULTS AREAS (KRAs)

- Policy formulation and implementation
- Standard setting
- Licensing and registration
- Inspection, testing and monitoring of products
- Human resource development

STRATEGIES

- **Inspection and licensing of BFAD-regulated establishments**
- **Evaluation, testing and registration of BFAD-regulated products**
- **Approval of product label**
- **Evaluation and monitoring of product advertisements and promotion**
- **Implementation of special laws i.e. Senior Citizen's Law, ASIN Law, Special Law on Counterfeit Drugs, Consumer Act and Generics Act**

COMPONENT DIVISIONS AND ITS SPECIFIC FUNCTIONS

I. Office of the Director

- **Over-all management, direction, supervision and control of the Bureau**

II. Administrative Division

- **General administrative and logistic support services such as personnel, finance, communication, documentation, security services and facilities operation and maintenance**

FUNCTIONS (cont. …)

III. Policy, Planning and Advocacy Division:

- **Review, update/develop policies relevant to BFAD jurisdiction**
- **Design plans and activities for implementing such policies and assess policy outcomes and impact**
- **Advocate activities and provide information and assistance to clients and the general public through the Consumer Information Unit**

FUNCTIONS (cont. …)

III. P P A D (cont.)

- **Post-marketing responsibilities**
  - * monitoring safety of products including monitoring of drug prices
  - * reporting adverse events/reactions
  - * product information

IV. Legal, Information and Compliance Division

- **Provide legal advice in the enforcement of BFAD laws, rules and regulations**
- **Conduct administrative proceedings and/or quasi-judicial hearings on BFAD cases**
- **Conduct administrative proceedings on cases involving BFAD personnel**

FUNCTIONS (cont. …)

IV. L I C D (cont. . .)

- **Prepare recommendations and/or resolutions and other administrative issuances for the BFAD director and the Secretary of Health.**
- **Investigate consumer complaints on products regulated by BFAD**
- **Monitor product advertisements and promotions to check compliance with existing guidelines on medical and nutritional claims**

FUNCTIONS (cont. …)

V. Laboratory Services Division

- **Conduct physico-chemical and microbiological analysis of food, drug, antibiotic, cosmetic and household hazardous substances.**

- **Evaluate results of analysis necessary for determining compliance with product safety, efficacy and quality standards**

- **Develop a harmonized standardization of quality control methods and procedures by participating in national and international proficiency testing program**

- **Establish a training program module in food, drug and cosmetic testing for new staff and for in-service trainees**

FUNCTIONS (cont. …)

V. Laboratory Services Division (cont…)

- **Conduct sterility test for parentals, opthalmic preparations and medical devices**
- **Determine the presence of contaminants both the naturally occurring toxicants and metals/chemicals from external source**
- **Perform the leachability and material testings of pharmaceutical and food packaging materials**
- **Produce properly-bred laboratory animals for toxicological examinations, bioassay and biological tests**
- **Issue Batch Cert’n of antibiotic products**

FUNCTIONS (cont. …)

VI. Product Services Division

- Establishment of standards for the registration of products regulated by BFAD to ensure that products are safe, effective and of good quality and that product labeling is truthful and informative
- Evaluation & processing of application for product registration and listing
- Issuance of certificates of product registration and certificates of product listing
- Assistance in the monitoring of violative products

FUNCTIONS (cont. …)

VII. Regulation Division I

- **Inspection & issuance of license to operate establishments dealing in the importation, exportation, distribution and retaling of products regulated by BFAD**
- **Collection of samples of products from outlets and ports of entry for quality monitoring**
- **Implementation of seizure, confiscation and condemnation orders covering violative products**
- **Conduct of training for FDROs from the different regional health offices**
- **Assistance in monitoring adverse drug reactions**

FUNCTIONS (cont. …)

VIII. Regulation Division II

- **Inspection and issuance of license to operate establishments dealing in the manufacture and repacking of products regulated by BFAD**
- **Monitoring of compliance with requirements of Good Manufacturing Practices (GMP)**
- **Implementation of seizure, confiscation and condemnation orders covering violative products**
- **Conduct of training for FDROs from the different regional health offices**

THANK YOU

&

HAVE A GOOD DAY