THE NEW FOOD AND DRUG ADMINISTRATION (FDA) OF THE REPUBLIC OF THE PHILIPPINES

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Introduction

- Republic Act (RA) 3720 of the Republic of the Philippines was amended with the passage of a new law, RA 9711 - “The Food and Drug Administration (FDA) Act of 2009”.
- The FDA Act of 2009 created the Food and Drug Administration (FDA) in the Department of Health (DOH) to be headed by a Director-General with the rank of Undersecretary of Health.
Major Aims of the FDA Act

• To protect and promote the right to health of the Filipino people
• To establish and maintain an effective health products regulatory system
Important Definitions in the FDA Act

• “Health products” means food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative thereof. It shall also refer to products that may have an effect on health which require regulations as determined by the FDA.

• “Device” means medical devices, radiation devices and health-related devices.
Resulting Major Changes

• New powers for the Food and Drug Administration.
• Major reorganization within the Department of Health.
Two Special Powers

Quasi-judicial Power

Power to retain and use its income for its operations, human resource development, creation of new positions, acquisition of new office and laboratory facilities and equipment, etc.
The FDA Act affected two existing DOH agencies

Bureau of Food and Drugs (BFAD) with regulatory functions over food, drugs, medical devices, cosmetics and household hazardous substances

Bureau of Health Devices and Technology (BHDT) with regulatory functions over radiation devices and radiation facilities

FOOD AND DRUG ADMINISTRATION (FDA) OF THE REPUBLIC OF THE PHILIPPINES
### The FDA Act created 4 Centers

1. Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biologicals)
2. Center for Food Regulation and Research
3. Center for Cosmetics Regulation and Research (to include household hazardous/urban substances)
The FDA Act also created 4 other units

- Field Regulatory Operations Office with a Regulatory Enforcement Unit per Regional Field Office
- Administration and Finance Office
- Policy and Planning Office
- Legal Services Center
What Has Been Done To Date by FDA

- Drafted the Implementing Rules and Regulations which were issued in September 2010.
- Held a Planning Workshop on Organizational Development and Change Management.
- Developed a five year business plan.
- Developed the staffing pattern with the estimated budget.
What FDA Is Currently Doing

• Preparing a five year work plan together with the estimated budget.
• Fine tuning the staffing pattern.
• Reviewing existing procedures, protocols, standards.
• Drafting a human resource development program.
• Preparing a laboratory development program.
The Center for Device Regulation, Radiation Health, and Research (CDRRHR)

**Major Functions of the CDRRHR**

- Regulation of the manufacture, import, export, distribution, promotion, advertisement, and sale of medical devices, radiation devices, and health-related devices
- Regulation of the use of radiation devices
- Health technology assessment of medical devices
What Has Been Done To Date for CDRRHR

Before the passage of the law, the BHDT

- had two WHO consultants who gave a series of lectures on existing regulatory frameworks for medical devices and recommended a new regulatory framework for medical devices.
- sent selected BHDT staff for on-the job training at the BFAD which was then regulating medical devices but only limited to 74 medical devices.
- sent a few staff members to Thailand, Singapore, Canada, and/or the USA to familiarize them with the medical device regulatory systems of those countries.

The BHDT has also

- Participated as a member in meetings of the ASEAN Consultative Committee on Standards and Quality – Medical Device Product Working Group since 2006.
- Participated as a member in the Asian Harmonization Working Party since 2002.
PLANNED MEDICAL DEVICE REGULATORY SYSTEM

Medical Device Establishment License as:
• Manufacturer
• Distributor/importer
• Distributor/wholesaler
• Retailer

• Timeline maximum 90 days including the on-site inspection

Medical Device Product Registration
• 4 Classifications (class 1,2,3,4)
• Registration is per product, per brand, per model (except if difference is in the sizes, and shapes)
• Timeline maximum 90 days (with complete documentary requirements)

Mandatory Reporting of Adverse Events and Product Recall

Post-market Surveillance – on-site visit to monitor the continuous compliance of the medical device establishments to the regulatory requirements

Target Date of Implementation: CY2011
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<th>Class 3</th>
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| Legal Requirements:  
• Notarized application form  
• License to operate as medical device establishment, issued by the CDRRHR  
• Notarized agreement with licensed local manufacturer and distributor  
• For imported medical devices, registration of product from issued by the health authority from the country of origin and foreign agency agreement both notarized and duly authenticated by the Philippine Consulate |
| Technical Requirements: (Based on the ASEAN Common Submission Dossier Template)  
• Device description  
• A description of the sterilization method and the packaging used, the sterility level and the validation of the sterilization process, if applicable.  
• Certificate of Conformity to the aspect of manufacture relating to metrology for devices with measuring functions  
• Declaration of Conformity with product standards, if applicable  
• Sample of labels on the device and its packaging and other labeling materials to be used for the device that includes user’s or instruction manuals  
• Government certificate attesting to the status of the Manufacturer’s competency and reliability of the personnel and facilities or Quality Systems Certificate of approval or compliance certificate with ISO 9000 series or ISO 13485. For imported medical device the Certificate shall be duly authenticated by the territorial Philippine Consulate  
• Stability studies of the product to justify claimed shelf-life, if applicable  
• Picture of the product and representative sample or commercial presentation of the product, when needed |

**Requirements for Registration of Medical Devices**

- Executive Summary
- Relevant essential principles and method/s used to demonstrate conformity, if applicable
- Device description
- Design Verification and Validation Documents
- Risk assessment consisting of risk analysis, evaluation and reduction measures, if applicable
- Manufacturer information including the process, quality assurance
- Clinical evidence, if applicable

Note:
Contents of design verification and validation documents, risk assessment, clinical evidence, biological evaluation, device description, and manufacturer’s information varies depending on the classification of the device

- Software validation studies, if applicable
- Biological evaluation, if applicable

- List of counties where the device has been sold.
MARAMING SALAMAT PO!

KHOB KHUN KA!

THANK YOU!