The New Food and Drug Administration of the Republic of the Philippines and its Role in Radiation Protection

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The new Food and Drug Administration of the Department of Health of the Republic of the Philippines created by law in 2009 has the mandate to regulate the manufacture, import, export, distribution, promotion, sale, and , where appropriate, use and testing of health products. Under this law, health products now include radiation devices. Radiation devices are defined as electrical or electronic apparatus emitting ionizing or non-ionizing radiation, or sound waves. This law also created the Center for Device Regulation, Radiation Health, and Research (CDRRHR) which was formed from what used to be a separate agency created in 1974. Its original function of regulating radiation devices and the facilities using these devices was retained. Provisions in the new law such as the creation of FDA regional offices with its own regulatory enforcement units and the granting of quasi-judicial power have strengthened the radiation protection mandate. The paper discusses in detail these and other relevant provisions of the law.

INTRODUCTION

In the Republic of the Philippines, the Department of Health (DOH) is the national government agency mandated to protect and promote the right to health of the people. Prior to 2009, the DOH had four regulatory bureaus. These were the Bureau of Health Facilities and Services, the Bureau of Food and Drugs (BFAD) , the Bureau of Quarantine, and the Bureau of Health Devices and Technology (BHDT). In 2009, the Food and Drug Administration Act became a law. It created the new Food and Drug Administration (FDA) in the DOH from what used to be BFAD and BHDT.

THE FDA ACT

Republic Act No. (RA) 9711, the Food and Drug Administration (FDA) Act, became a law in 2009. Its Implementing Rules and Regulations were issued in 2011. RA 9711 amended RA 3720, Presidential Decrees 480 and 1372.

The law gave FDA regulatory and quasi-judicial power over health products and health product establishments.

Included in the law is the definition of terms which include the following terms: **1. health products** - "food, drugs, cosmetics, devices, biologicals, vaccines, in-vitro diagnostic reagents, 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." **2. device** – "medical devices, radiation devices and health-related devices." **3. radiation device** - **" an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic or particulate radiation; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation emitting equipment which is not intentionally designed to produce radioactive materials."**

PROVISIONS OF THE FDA ACT STRENGTHENING REGULATION AND ENFORCEMENT

1. Creation of FDA regional field offices nationwide, all with a licensing, inspection and compliance division thus bringing FDA nearer the location of its clients.
2. Creation in each FDA regional field office of an enforcement unit to be headed by a lawyer and staffed with personnel allowed to bear arms.
3. Creation under the Office of the Director General of the Legal Services Support Center to assume quasi-judicial functions.
4. Creation of FDA regional field offices nationwide, all with a licensing, inspection and compliance division thus bringing FDA nearer the location of its clients.
5. Creation in each FDA regional field office of an enforcement unit to be headed by a lawyer and staffed with personnel allowed to bear arms.
6. Creation under the Office of the Director General of the Legal Services Support Center to assume quasi-judicial functions.
7. Stronger Penalties
   a. Administrative penalties imposed by the FDA Director-General:

(1) "The seizure and condemnation, destruction and/or appropriate disposition of the subject health product;

(2) The imposition of an administrative fine in such amount as deemed reasonable, which shall in no case be less then Fifty Thousand Pesos… nor more than Five Hundred Thousand Pesos… depending on the gravity of the offense, and the additional administrative fine of not more than One Thousand Pesos for each day of continuing violation;

(3) Suspension of the validity of the License to Operate (LTO), Certificate of Product Registration (CPR), or other appropriate authorizations for a period which shall not exceed one year;

(4) Revocation of the LTO, CPR or appropriate authorizations;

(5) Closure of the establishment;

(6) Other penalties provided by relevant laws being administered by the FDA."

b. Penal sanctions imposed by the Court:

(1) Imprisonment of one year but not more than ten years;

(2) Fines of fifty thousand pesos up to five million pesos;

(3) Both (1) and (2)

(4) Additional fine of one percent of the economic value/cost of the violative product or violation or one thousand pesos, whichever is higher, per day of continuing violation

(5) Seizure and condemnation, destruction and/or appropriate disposition of the subject health product "without hearing or court order…"

8. Authority to retain and utilize its income

CHALLENGES AHEAD

1. Submission of the final FDA Five-Year Business Plan which includes the personnel complement that would merit the approval of the Department of Budget and Management.
2. Effective regulation of all health products and health product establishments which need to be regulated.
3. Effective implementation and enforcement of the FDA Act and other pertinent laws and regulations.
4. Keeping pace with developments in the field.
5. Retention of qualified personnel.
6. Training and development of newly- and currently-employed personnel.
7. Upgrading and expanding its laboratory capabilities.

REFERENCES

The Food and Drug Administration Act of 2009

Presidential Decree No. 480 "Creating a Radiation Health Office in the Department of Health"

Presidential Decree No. 1372 "Amending Presidential Decree No. 480"