APPENDIX A

Republic of the Philippines
Congress of the Philippines
Metro Manila

Eighth Congress

Republic Act No. 6969 **October 26, 1990**

AN ACT TO CONTROL TOXIC SUBSTANCES AND HAZARDOUS AND NUCLEAR WASTES, PROVIDING PENALTIES FOR VIOLATIONS THEREOF, AND FOR OTHER PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled::

Section 1. ***Short title.*** – This Act shall be known as the **"*Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990*."**

Section 2. ***Declaration of Policy*.** – It is the policy of the State to regulate, restrict or prohibit the importation, manufacture, processing, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk and/or injury to health or the environment; to prohibit the entry, even in transit, of hazardous and nuclear wastes and their disposal into the Philippine territorial limits for whatever purpose; and to provide advancement and facilitate research and studies on toxic chemicals.

Section 3. ***Scope.*** – This Act shall cover the importation, manufacture, processing, handling, storage, transportation, sale, distribution, use and disposal of all unregulated chemical substances and mixtures in the Philippines, including the entry, even in transit as well as the keeping or storage and disposal of hazardous and nuclear wastes into the country for whatever purpose.

Section 4. ***Objectives*.** – The objectives of this Act are:

a) To keep an inventory of chemicals that are presently being imported, manufactured, or used, indicating, among others, their existing and possible uses, test data, names of firms manufacturing or using them, and such other information as may be considered relevant to the protection of health and the environment;

b) To monitor and regulate the importation, manufacture, processing, handling, storage, transportation, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk or injury to health or to the environment in accordance with national policies and international commitments;

c) To inform and educate the populace regarding the hazards and risks attendant to the manufacture, handling, storage, transportation, processing, distribution, use and disposal of toxic chemicals and other substances and mixture; and

d) To prevent the entry, even in transit, as well as the keeping or storage and disposal of hazardous and nuclear wastes into the country for whatever purpose.

Section 5. ***Definition*.** – As used in this Act:

a) Chemical substance means any organic or inorganic substance of a particular molecular identity, including:

i) Any combination of such substances occurring in whole or in part as a result of chemical reaction or occurring in nature; and

ii) Any element or uncombined chemical.

b) Chemical mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction, if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been

manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined. This shall include nonbiodegradable mixtures.

c) Process means the preparation of a chemical substance or mixture after its manufacture for commercial distribution:

i) In the same form or physical state or in a different form or physical state from that which it was received by the person so preparing such substance or mixture; or

ii) As part of an article containing a chemical substance or mixture.

d) Importation means the entry of a products or substances into the Philippines (through the seaports or airports of entry) after having been properly cleared through or still remaining under customs control, the product or substance of which is intended for direct consumption, merchandising, warehousing, or for further processing.

e) Manufacture means the mechanical or chemical transformation of substances into new products whether work is performed by power-driven machines or by hand, whether it is done in a factory or in the worker's home, and whether the products are sold at wholesale or retail.

f) Unreasonable risk means expected frequency of undesirable effects or adverse responses arising from a given exposure to a substance.

g) Hazardous substances are substances which present either:

1) short-term acute hazards, such as acute toxicity by ingestion, inhalation or skin absorption, corrosivity or other skin or eye contact hazards or the risk of fire or explosion; or

2) long-term environmental hazards, including chronic toxicity upon repeated exposure, carcinogenicity (which may in some cases result from acute exposure but with a long latent period), resistance to detoxification process such as biodegradation, the potential to pollute underground or surface waters, or aesthetically objectionable properties such as offensive odors.

h) Hazardous wastes are hereby defined as substances that are without any safe commercial, industrial, agricultural or economic usage and are shipped, transported or brought from the country of origin for dumping or disposal into or in transit through any part of the territory of the Philippines.

Hazardous wastes shall also refer to by-products, side-products, process residues, spent reaction media, contaminated plant or equipment or other substances from manufacturing operations, and as consumer discards of manufacture products.

i) Nuclear wastes are hazardous wastes made radioactive by exposure to the radiation incidental to the production or utilization of nuclear fuels but does not include nuclear fuel, or radioisotopes which have reached the final stage of fabrication so as to be usable for any scientific, medical, agricultural, commercial, or industrial purpose.

Section 6. ***Function, Powers and Responsibilities of the Department of Environment and Natural Resources.*** – The Department of Environment and Natural Resources shall be the implementing agency tasked with the following functions, powers, and responsibilities:

a) To keep an updated inventory of chemicals that are presently being manufactured or used, indicating, among others, their existing and possible uses, quality, test data, names of firms manufacturing or using them, and such other information as the Secretary may consider relevant to the protection of health and the environment;

b) To require chemical substances and mixtures that present unreasonable risk or injury to health or to the environment to be tested before they are manufactured or imported for the first time;

c) To require chemical substances and mixtures which are presently being manufactured or processed to be tested if there is a reason to believe that they pose unreasonable risk or injury to health or the environment;

d) To evaluate the characteristics of chemicals that have been tested to determine their toxicity and the extent of their effects on health and the environment;

e) To enter into contracts and make grants for research, development, and monitoring of chemical substances and mixtures;

f) To conduct inspection of any establishment in which chemicals are manufactured, processed, stored or held before or after their commercial distribution and to make recommendations to the proper authorities concerned;

g) To confiscate or impound chemicals found not falling within said acts cannot be enjoined except after the chemicals have been impounded;

h) To monitor and prevent the entry, even in transit, of hazardous and nuclear wastes and their disposal into the country;

i) To subpoena witnesses and documents and to require other information if necessary to carry out the provisions of this Act;

j) To call on any department, bureau, office, agency, state university or college, and other instrumentalities of the Government for assistance in the form of personnel, facilities, and other resources as the need arises in the discharge of its functions;

k) To disseminate information and conduct educational awareness campaigns on the effects of chemical substances, mixtures and wastes on health and environment; and

l) To exercise such powers and perform such other functions as may be necessary to carry out its duties and responsibilities under this Act.

Section 7. ***Inter-Agency Technical Advisory Council.*** – There is hereby created an Inter-Agency Technical Advisory Council attached to the Department of Environment and Natural Resources which shall be composed of the following officials or their duly authorized representatives:

Secretary of Environment and Natural Resources	Chairman
Secretary of Health	Member
Director of the Philippine Nuclear Research Institute	Member
Secretary of Trade and Industry	Member
Secretary of Science and Technology	Member
Secretary of National Defense	Member
Secretary of Foreign Affairs	Member
Secretary of Labor and Employment	Member
Secretary of Finance	Member
Secretary of Agriculture	Member
Representative from a non-governmental organization on health and safety	Member

The representative from the non-governmental organization shall be appointed by the President for a term of three (3) years.

The Council shall have the following functions:

a) To assist the Department of Environment and Natural Resources in the formulation of the pertinent rules and regulations for the effective implementation of this Act;

b) To assist the Department of Environment and Natural Resources in the preparation and updating of the inventory of chemical substances and mixtures that fall within the coverage of this Act;

c) To conduct preliminary evaluation of the characteristics of chemical substances and mixtures to determine their toxicity and effects on health and the environment and make the necessary recommendations to the Department of Environment and Natural Resources; and

d) To perform such other functions as the Secretary of Environment and Natural Resources may, from time to time, require.

Section 8. ***Pre-Manufacture and Pre-Importation Requirements.*** – Before any new chemical substance or mixture can be manufactured, processed or imported for the first time as determined by the Department of Environment and Natural Resources, the manufacturer, processor or importer shall submit the following information: the name of the chemical substance or mixture; its chemical identity and molecular structure; proposed categories of use; an estimate of the amount to be manufactured, processed or imported; processing and disposal thereof; and any test data related to health and environmental effects which the manufacturer, processor or importer has.

Section 9. ***Chemicals Subject to Testing.*** – Testing shall be required in all cases where:

a) There is a reason to believe that the chemical substances or mixture may present an unreasonable risk to health or the environment or there may be substantial human or environmental exposure thereto;

b) There are insufficient data and experience for determining or predicting the health and environmental effects of the chemical substance or mixture; and

c) The testing of the chemical substance or mixture is necessary to develop such data.

The manufacturers, processors or importers shall shoulder the costs of testing the chemical substance or mixture that will be manufactured, processed, or imported.

Section 10. ***Action by the Secretary of Environment and Natural Resources of his Duly Authorized Representative.*** – The Secretary of Environment and Natural Resources or his duly authorized representative shall, within ninety (90) days from the date of filing of the notice of manufacture, processing or importation of a chemical substance or mixture, decide whether or not to regulate or prohibit its importation, manufacture, processing, sale, distribution, use or disposal. The Secretary may, for justifiable reasons, extend the ninety-day pre-manufacture period within a reasonable time.

Section 11. ***Chemical Substances Exempt from Pre-Manufacture Notification.*** – The manufacture of the following chemical substances or mixtures shall be exempt from pre-manufacture notification:

a) Those included in the categories of chemical substances and mixtures already listed in the inventory of existing chemicals;

b) Those to be produced in small quantities solely for experimental or research and developmental purposes;

c) Chemical substances and mixtures that will not present an unreasonable risk to health and the environment; and

d) Chemical substances and mixtures that exist temporarily and which have no human or environmental exposure such as those which exist as a result of chemical reaction in the manufacture or processing of a mixture of another chemical substance.

Section 12. ***Public Access to Records, Reports or Notification.*** – The public shall have access to records, reports, or information concerning chemical substances and mixtures including safety data submitted, data on emission or discharge into the environment, and such documents shall be available for inspection or reproduction during normal business hours except that the Department of Environment and Natural resources may consider a record, report or information or particular portions thereof confidential and may not be made public when such would divulge trade secrets, production or sales figures or methods, production or processes unique to such manufacturer, processor or distributor, or would otherwise tend to affect adversely the competitive position of such manufacturer, processor or distributor. The Department of Environment and Natural Resources, however, may release information subject to claim of confidentiality to a medical research or scientific institution where the information is needed for the purpose of medical diagnosis or treatment of a person exposed to the chemical substance or mixture.

Section 13. ***Prohibited Acts.*** – The following acts and omissions shall be considered unlawful:

a) Knowingly use a chemical substance or mixture which is imported, manufactured, processed or distributed in violation of this Act or implementing rules and regulations or orders;

b) Failure or refusal to submit reports, notices or other information, access to records, as required by this Act, or permit inspection of establishment where chemicals are manufactured, processed, stored or otherwise held;

c) Failure or refusal to comply with the pre-manufacture and pre-importation requirements; and

d) Cause, aid or facilitate, directly or indirectly, in the storage, importation, or bringing into Philippines territory, including its maritime economic zones, even in transit, either by means of land, air or sea transportation or otherwise keeping in storage any amount of hazardous and nuclear wastes in any part of the Philippines.

Section 14. ***Criminal Offenses and Penalties*****.** –

a) (i) The penalty of imprisonment of six (6) months and one day to six (6) years and one day and a fine ranging from Six hundred pesos (P600.00) to Four thousand pesos (P4,000.00) shall be imposed upon any person who shall violate section 13 (a) to (c) of this Act and shall not be covered by the Probation Law.f the offender is a foreigner, he or she shall be deported and barred from any subsequent entry into the Philippines after serving his or her sentence;

ii) In case any violation of this Act is committed by a partnership, corporation, association or any juridical person, the partner, president, director or manager who shall consent to or shall knowingly tolerate such violation shall be directly liable and responsible for the act of the employee and shall be criminally liable as a co-principal;

(iii) In case the offender is a government official or employee, he or she shall, in addition to the above penalties, be deemed automatically dismissed from office and permanently disqualified from holding any elective or appointive position.

b) (i) The penalty of imprisonment of twelve (12) years and one day to twenty (20) years, shall be imposed upon any person who shall violate section 13 (d) of this Act.f the offender is a foreigner, he or she shall be deported and barred from any subsequent entry into the Philippines after serving his or her sentence;

(ii) In the case of corporations or other associations, the above penalty shall be imposed upon the managing partner, president or chief executive in addition to an exemplary damage of at least Five hundred thousand pesos (P500,000.00).f it is a foreign firm, the director and all officers of such foreign firm shall be barred from entry into the Philippines, in addition to the cancellation of its license to do business in the Philippines;

(iii) In case the offender is a government official or employee, he or she in addition to the above penalties be deemed automatically dismissed from office and permanently disqualified from holding any elective or appointive position.

c) Every penalty imposed for the unlawful importation, entry, transport, manufacture, processing, sale or distribution of chemical substances or mixtures into or within the Philippines shall carry with it the confiscation and forfeiture in favor of the Government of the proceeds of the unlawful act and instruments, tools or other improvements including vehicles, sea vessels, and aircrafts used in or with which the offense was committed. Chemical substances so confiscated and forfeited by the Government at its option shall be turned over to the Department of Environment and Natural resources for safekeeping and proper disposal.

d) The person or firm responsible or connected with the bringing or importation into the country of hazardous or nuclear wastes shall be under obligation to transport or send back said prohibited wastes;

Any and all means of transportation, including all facilities and appurtenances that may have been used in transporting to or in the storage in the Philippines of any significant amount of hazardous or nuclear wastes shall at the option of the government be forfeited in its favor.

Section 15. ***Administrative Fines*****.** – In all cases of violations of this Act, including violations of implementing rules and regulations which have been duly promulgated and published in accordance with Section 16 of this Act, the Secretary of Environment and Natural Resources is hereby authorized to impose a fine of not less than Ten thousand pesos (P10,000.00), but not more than Fifty thousand pesos (P50,000.00) upon any person or entity found guilty thereof. The administrative fines imposed and collected by the Department of Environment and Natural Resources shall accrue to a special fund to be administered by the Department exclusively for projects and research activities relative to toxic substances and mixtures.

Section 16. *Promulgation of Rules and Regulations*. – The Department of Environment and Natural Resources, in coordination with the member agencies of the Inter-Agency Technical Advisory Council, shall prepare and publish the rules and regulations implementing this Act within six months from the date of its effectivity.

Section 17. *Appropriations*. – Such amount as may be necessary to implement the provisions of this Act is hereby annually appropriated and included in the budget of the Department of Environment and Natural Resources.

Section 18. *Separability Clause*. – If any provision of this Act is declared void or unconstitutional, the remaining provisions thereof not affected thereby shall remain in full force and effect.

Section 19. *Repealing Clause*. – All laws, presidential decrees, executive orders and issuances, and rules and regulations which are inconsistent with this Act are hereby repealed or modified accordingly.

Section 20. *Effectivity*. – This Act shall take effect after fifteen (15) days following its publication in the Official Gazette or in any newspaper of general circulation.

Approved: **October 26, 1990**

APPENDIX B

MALACAÑANG
M a n i l a

PRESIDENTIAL DECREE No. 1144

CREATING THE FERTILIZER AND PESTICIDE AUTHORITY AND ABOLISHING THE FERTILIZER INDUSTRY AUTHORITY

WHEREAS, it is a Government policy to provide adequate assistance to the agricultural sector in line with national objective of increasing food production;

WHEREAS, fertilizer and pesticides as vital inputs in food production and must be supplied in adequate quantities at reasonable costs.

WHEREAS, improper pesticide usage presents serious risks to users, handlers, and the public in general because of the inherent toxicity of these compounds which are, moreover, potential environmental contaminants;

WHEREAS, there is a need to educate the agricultural sector on the benefits as well as the hazards of pesticide use so that it can utilized pesticides properly to promote human welfare while avoiding dangers to health and environmental pollution;

WHEREAS, the fertilizer and pesticide industries have much in common in terms of clientele, distribution channels, system of application in farmers' fields, and technical supervision by the same farm management technicians under the government's food production program;

WHEREAS, the foregoing considerations make it desirable to have one agency to regulate fertilizer importation, manufacture, formulation, distribution, delivery, sale, transport and storage as well as pesticide labeling, distribution, storage, transportation, use and disposal;

WHEREAS, the Fertilizer Industry Authority was created by Presidential Decree No. 135, dated 22 February 1973, and amended by Presidential Decree Nos. 517 and 669, dated 19 July 1974 and 11 March 1975 respectively, in order to regulate, control and develop the fertilizer industry but does not include the pesticide industry in its jurisdiction;

WHEREAS, there is an urgent need to create a technically-oriented government authority equipped with the required expertise to regulate, control and develop both the fertilizer and the pesticide industries;

NOW, THEREFORE, I, FERDINAND E. MARCOS, President of the Philippines, by virtue of the powers vested in me by the Constitution, do hereby decree and order the following:

Section 1. *Creation of the Fertilizer and Pesticide Authority.* The Fertilizer and Pesticide Authority, hereinafter referred to as the FPA, is hereby created and attached to the Department of Agriculture for the purpose of assuring the agricultural sector of adequate supplies of fertilizer and pesticide at reasonable prices, rationalizing the manufacture and marketing of fertilizer, protecting the public from the risks inherent in the use of pesticides, and educating the agricultural sector in the use of these inputs.

Section 2. *Abolition of the Fertilizer Industry Authority.* The Fertilizer Industry Authority created under Presidential Decree 135, dated 22 February 1973, as amended by Presidential Decree 517 and 669, dated 19 July 1974 and 11 March 1975 respectively, is hereby abolished.

The FPA shall assume such appropriations, assets and liabilities and hire such personnel of the FIA as may be determined by its Board of Directors; Provided, that such assumption is made within sixty (60) days from the effectivity of this decree.

Section 3. *Definitions.* For the purpose hereof, the terms herein below shall be understood to mean as follows:

> **(a) "Pesticide" any substance or product, or mixture thereof, including active ingredients, adjuvants, and pesticide formulations, intended to control, prevent, destroy, repel or mitigate directly or indirectly,**

any pest. The term shall be understood to include insecticide, fungicide, bactericide, nematocide, herbicide, molluscicide, avicide, rodenticide, plant regulator, defoliant, desiccant and the like.

(b) "Fertilizer" includes any substance solid or liquid or any nutrient element or elements organic or inorganic singly or in combination with other materials, applied directly to the soil for the purpose of promoting plant growth, increasing crop yield or improving their quality.

(c) "Other agricultural chemicals" shall mean chemicals, chemical inputs and chemical compounds not herewith covered by the definition of fertilizer and pesticide but utilized by the agricultural sector.

(d) "Handlers" shall mean exporters, importers, manufacturers, formulators, distributors, suppliers, wholesalers, dealers, repackers, commercial applicators, warehousers, and retailer of fertilizers, fertilizer inputs, pesticide and other agricultural inputs.

(e) "Tolerance Level" shall mean the maximum amount of pesticides, as determined by the FPA, which may be allowed to remain in any raw agricultural produce at any stage between harvesting and consumption.

(f) "Imminent Hazard" shall mean a situation which exists when the continued use of a pesticide will likely result in unreasonable adverse effects on the public and/or the environment or will involve unreasonable hazards to the survival of a specie declared endangered by the appropriate authorities.

Section 4. ***Board of Directors.*** **The powers and functions of the FPA shall be vested in and exercised by a Board of Directors which shall be composed of the following officials or their representatives:**

1.	Secretary of Agriculture	Chairman
2.	Secretary of Industry	Member
3.	Secretary of Finance	Member
4.	Secretary of Trade	Member
5.	Governor, Central Bank	Member
6.	President, Philippine National Bank	Member
7.	Director, Bureau of Plant Industry	Member
8.	Commissioner, Pollution Control Commission	Member
9.	Administrator, Food & Drug Administration	Member

The members of the Board shall elect a Vice-Chairman who shall act as Chairman in case of the absence, inability or temporary incapacity of the Chairman.

Section 5. *Organization.* The FPA is empowered to determine and create its organizational structure in order to achieve its objectives, including the number, positions and salaries of its officers and employees.

The Board is empowered to create the positions of Administrator, Deputy Administrator for Fertilizer, Deputy Administrator for Pesticides, and other subordinate officials as may be required.

The Board shall appoint all the officers of the FPA, establish a compensation scheme including allowances and benefits, working hours and such other conditions of employment as it may deem proper, discipline and/or removed for cause, and exercise such other powers over its personnel as may be necessary for the efficient operation of the FPA.

Section 6. *Powers and Functions.* The FPA shall have jurisdiction, on over all existing handlers of pesticides, fertilizers and other agricultural chemical inputs. The FPA shall have the following powers and functions:

I. Common to Fertilizers, Pesticides and other Agricultural Chemicals.

(1) To conduct an information campaign regarding the safe and effective use of these products;

(2) To promote and coordinate all fertilizer and pesticides research in cooperation with the Philippine Council for Agriculture and Resources Research and other appropriate agencies to ensure scientific pest control in the public interest, safety in the use and handling of pesticides, higher standards and quality of products and better application methods;

(3) To call upon any department, bureau, office, agency or instrumentality of the government, including government-owned or controlled corporations, or any officer or employee thereof and on the private sector, for such information or assistance as it may need in the exercise of its powers and in the performance of its functions and duties;

(4) To promulgate rules and regulations for the registration and licensing of handlers of these products, collect fees pertaining thereto, as well as the renewal, suspension, revocation, or cancellation of such registration or licenses and such other rules and regulations as may be necessary to implement this Decree;

(5) To establish and impose appropriate penalties on handlers of these products for violations of any rules and regulations established by the FPA;

(6) To institute proceedings against any person violating any provisions of this Decree and/or such rules and regulations as may be promulgated to implement the provisions of this Decree after due notice and hearing.

(7) To delegate such selected privileges, powers or authority as may be allowed by law to corporation, cooperatives, associations or individuals as may presently exist or be organized to assist the FPA in carrying out its functions, and;

(8) To do any and all acts not contrary to law or existing decrees and regulations as may be necessary to carry out the functions of the FPA.

II. Fertilizers

(1) To make a continuous assessment of the fertilizer supply and demand situation, both domestic and worldwide;

(2) To establish and enforce sales quotas, production schedules, distributions areas and such other marketing regulations as maybe necessary to assure market stability and viable operations in the industry;

(3) To determine and set the volume and prices both wholesale and retail; of fertilizer and fertilizer inputs;

(4) To establish and implement regulations governing the import and export of fertilizer and fertilizer inputs, and when necessary, to itself import and/or export such items, including the negotiating and contracting of such imports and exports;

(5) To import fertilizer and fertilizer inputs exempt from customs duties, compensating and sales taxes and all other taxes, and to purchase naptha locally free from specific taxes and the corresponding duty on the imported crude, and to sell or convey such fertilizer or fertilizer input to any individual association, or corporation likewise exempt from the payment of customs duties and all other taxes;

(6) To control and regulate all marketing companies, whether importer, indentor, wholesaler or retailer; by controlling and regulating prices, terms, mark-ups, distribution channels, promotion, storage and other marketing factors in the domestic fertilizer market;

(7) To regulate and control quality of the different grades of fertilizer and to set new grades when necessary;

(8) To control and regulate all aspects of domestic fertilizer production, including the utilization of idle capacity and the orderly expansion of the industry and to compel the utilization of unused or

underutilized capacities of fertilizer companies and to direct any improvements, modifications or repairs as may be necessary to accomplish this;

(9) To approve or to reject the establishment of new fertilizer or fertilizer input plants and the expansion or contraction of existing capacities;

(10) To obtain complete assess to all pertinent information on the operations of the industry, including audited and/or unaudited financial statements, marketing, production, and inventory data;

(11) To control and assist in the financing of the importation of fertilizer and fertilizers inputs of production, of inventory and working capital, and of the expansion of the industry;

(12) To do all such things as may be necessary to maintain an adequate supply of fertilizers to the domestic market at reasonable prices while maintaining the long-term viability of the industry.

III. Pesticides and Other Agricultural Chemicals

(1) To determine specific uses or manners of use for each pesticide or pesticide formulation;

(2) To establish and enforce tolerance levels and good agricultural practices for use of pesticides in raw agricultural commodities.

(3) To restrict or ban the use of any pesticide or the formulation of certain pesticides in specific areas or during certain periods upon evidence that the pesticide is an imminent hazard, has caused, or is causing widespread serious damage to crops, fish or livestock, or to public health and the environment;

(4) To prevent the importation of agricultural commodities containing pesticide residues above the accepted tolerance levels and to regulate the exportation of agricultural products containing pesticide residue above accepted tolerance levels;

(5) To inspect the establishment and premises of pesticide handlers to insure that industrial health and safety rules and anti-pollution regulations are followed;

(6) To enter and inspect farmers' fields to ensure that only the recommended pesticides are used in specific crops in accordance with good agricultural practice;

(7) To require if and when necessary, of every handler of these products, the submission to the FPA of a report stating the quantity, value of each kind of product exported, imported, manufactured, produced, formulated, repacked, stored, delivered, distributed, or sold;

(8) Should there by any extraordinary and unreasonable increases in prices or a severe shortage in supply of pesticides, or imminent dangers or either occurrences, the FPA is empowered to impose such controls as may be necessary in the public interest, including but not limited to such restrictions and controls as the imposition of price ceilings, controls on inventories, distribution and transport, and tax-free importations of such pesticides or raw materials thereof as may be in short supply.

Section 7. *Power to Issue Rules and Regulations to Implement Decree.* The FPA is hereby authorized to issue or promulgate rules and regulations to implement, and carry out the purposes and provisions of this Decree.

Section 8. *Prohibitions Governing Sale and Use of Fertilizers and Pesticides.* It shall be unlawful for any handler of pesticides, fertilizer, and other agricultural chemicals or for any farmers, planter or end-user of the same as the case may be:

(a) To engage in any form of production, importation, distribution, storage and sale in commercial quantities without securing from the FPA a license therefor;

(b) To use any pesticide or pesticide formulation on crops, livestock, and the environment in a manner contrary to good agricultural practices as hereinabove defined;

(c) To deal in pesticides and/or fertilizers which have not been previously registered with FPA, or which registration has expired or has been suspended or revoked;

(d) To adulterate pesticides formulation and fertilizer grade;

(e) To impose as a condition for the purchase of fertilizer, the simultaneous purchase of pesticide for other agricultural chemical inputs and vice-versa;

(f) To mislable or make claims which differ in substance from the representation made in connection with a product's registration or from its actual effectiveness; and

(g) To violate such other rules and regulations as may be promulgated by FPA.

Section 9. *Registration and Licensing.* No pesticides, fertilizer, or other agricultural chemical shall be exported, imported, manufactured, formulated, stored distributed, sold or offered for sale, transported, delivered for transportation or used unless it has been duly registered with the FPA or covered by a numbered provisional permit issued by FPA for use in accordance with the conditions as stipulated in the permit. Separate registrations shall be required for each active ingredient and its possible formulations in the case of pesticides or for each fertilizer grade in the case of fertilizer.

No person shall engage in the business of exporting, importing, manufacturing, formulating, distributing, supplying, repacking, storing, commercially applying, selling, marketing, of any pesticides, fertilizer and other agricultural chemicals except under a license issued by the FPA.

The FPA, in the pursuit of its duties and functions, may suspend, revoke, or modify the registration of any pesticide, fertilizer and other agricultural chemicals after due notice and hearing.

Section 10. *Penalties*

(a) Fertilizer. Any person who violates any of the provisions of this Decree or any of the provisions of the rules and regulations issued or promulgated by the FPA on fertilizer shall be punished by imprisonment of not less than 15 years and 1 day or more than 20 years if the amount involved is more than P50,000.00; by imprisonment of not less than 10 years and 1 day or more than 15 years if the amount involved is P10,000.00 or less, as well as a fine ranging from an amount equal to the value involved to three times such value but which shall in no case be less than P5,000.00 nor more than P20,000.00; by a fine of P5,000.00 but not more than P10,000.00 by other violations where the amount involved cannot be determined; Provided, that if falsification of a public or commercial document is committed by reasons or on the occasion of the commission of any of the acts punishable herein, the offender shall be imposed of the maximum fine and term of imprisonment as above prescribed. If the violation is committed by a corporation, firm, partnership, cooperative, association or any other entity, the penalty shall be imposed upon the guilty office or offices and such corporation, firm, partnership, association or entity.

(b) Pesticides. Any person who violates any of the provisions of this Decree or any of the provisions of the rules and regulations issued or promulgated by FPA or pesticide, shall be liable to a penal servitued of not in excess of one year or a fine of P5,000.00 but not more than P10,000.00 provided that if the violation is committed by a corporation, firm, partnership, cooperative, association or any other entity, the penalty shall be imposed upon the guilty officials or officers of such entities.

Section 11. *Appropriation.* The sum of One Million and Two Hundred Thousand (P1.2 Million) Pesos shall, in addition to what has been appropriated for the Fertilizer Industry Authority for the Calendar Year 1977, be released out of any funds in the National Treasury not otherwise appropriated. For every calendar year thereafter such sums as may be necessary for the operations of the FPA shall be included in the General Appropriations Decree.

Any provision of existing law to the contrary notwithstanding, the FPA may impose fees or receive grants, subsidies, donations, or contributions from any entity and retain such funds for its operation.

Section 12. *Life of FPA.* The FPA shall constitute itself immediately and shall continue to exist until and unless abolished by the President of the Philippines.

Section 13. *Separability Clause.* The provisions of this Decree are hereby declared to be separable, and in the event any one of more of such provisions are held unconstitutional, the validity of other provisions shall not be affected.

Section 14. *Repealing Clause.* All laws, decrees, acts, executive order, ordinances, rules and regulations which are inconsistent with the provisions of the Presidential Decree are hereby repealed, amended or modified accordingly.

Section 15. *Effectivity.* This Decree shall take effect upon approval.

Done in the City of Manila, this 30th day of May, in the year of Our Lord, nineteen hundred and seventy-seven.

APPENDIX C

Republic of the Philippines
Congress of the Philippines
Metro Manila

Fourteenth Congress
Second Regular Session

Begun and held in Metro Manila, on Monday, the twenty-eighth day of July, two thousand eight.

Republic Act No. 9711 August 18, 2009

AN ACT STRENGTHENING AND RATIONALIZING THE REGULATORY CAPACITY OF THE BUREAU OF FOOD AND DRUGS (BFAD) BY ESTABLISHING ADEQUATE TESTING LABORATORIES AND FIELD OFFICES, UPGRADING ITS EQUIPMENT, AUGMENTING ITS HUMAN RESOURCE COMPLEMENT, GIVING AUTHORITY TO RETAIN ITS INCOME, RENAMING IT THE FOOD AND DRUG ADMINISTRATION (FDA), AMENDING CERTAIN SECTIONS OF REPUBLIC ACT NO. 3720, AS AMENDED, AND APPROPRIATING FUNDS THEREOF

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled::

Section 1. The Bureau of Food and Drugs (BFAD) is hereby renamed the Food and Drug Administration (FDA).

Section 2. This Act shall be known as the **"*Food and Drug Administration (FDA) Act of 2009*"**.

Section 3. It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments, and the registration and monitoring of health products.

Section 4. This Act has the following objectives:

(a) To enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction;

(b) To ensure the FDA's monitoring and regulatory coverage over establishments and products under its jurisdiction; and

(c) To provide coherence in the FDA's regulatory system for establishments and products under its jurisdiction.

Section 5. Section 4 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 4. To carry out the provisions of this Act, there is hereby created an office to be called the Food and Drug Administration (FDA) in the Department of Health (DOH). Said Administration shall be under the Office of the Secretary and shall have the following functions, powers and duties:

"(a) To administer the effective implementation of this Act and of the rules and regulations issued pursuant to the same;

"(b) To assume primary jurisdiction in the collection of samples of health products;

"(c) To analyze and inspect health products in connection with the implementation of this Act;

"(d) To establish analytical data to serve as basis for the preparation of health products standards, and to recommend standards of identity, purity, safety, efficacy, quality and fill of container;

"(e) To issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products, as determined by the FDA;

"x x x

"(h) To conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality;

"(i) To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person;

"(j) To issue cease and desist orders *motu propio* or upon verified complaint for health produts, whether or not registered with the FDA *Provided*, That for registered health products, the cease and desist order is valid for thirty (30) days and may be extended for sixty (60) days only after due process has been observed;

"(k) After due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;

"(l) To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products;

"(m) To develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products;

"(n) To conduct, supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA;

"(o) To prescribe standards, guidelines, and regulations with respect to information, advertisements and other marketing instruments and promotion, sponsorship, and other marketing activities about the health products as covered in this Act;

"(p) To maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry; and

"(q) To exercise such other powers and perform such other functions a8 may be necessary to carry out its duties and responsibilities under this Act."

Section 6. Section 5 of Republic Act No. 3720, as amended, is hereby further amended and new subsections are added to read as follows:

"SEC. 5. The FDA shall have the following centers and offices:

"(a) The Centers shall be established per major product category that is regulated, namely:

"(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); and

"(4) Center for Device Regulation, Radiation Health, and Research.

"These Centers shall regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products. The Centers shall likewise conduct research on the safety, efficacy, and quality of health products, and to institute standards for the same.

"(b) Each Center shall be headed by a director. The Centers shall be so organized such that each will have, at least, the following divisions:

"(1) Licensing and Registration Division, which shall be responsible for evaluating health products and establishments as covered by this Act for the purpose of issuance of authorizations and conditions to be observed;

"(2) Product Research and Standards Development Division, which shall be responsible for the conduct of research, development of standards and regulations, compliance monitoring, and the oversight and audit of related researches that would ensure safety, quality, purity and efficacy of health products, as covered in this Act; and

"(3) Laboratory Support Division, which shall be responsible for the conduct of research and appropriate testa and calibration, analyses and trials of products including, but not limited to, assays, and the conduct of oversight and/or audit of centers conducting bioavailability and bioequivalence tests and other tests as covered by this Act. It shall likewise provide direct line support to the centers which shall be separate and distinct per major product category that is regulated.

"(c) The Administration and Finance Office headed by the deputy director-general for administration and finance shall have, at least, the following divisions: the Human Resource Development Division; Property and Logistics Management Division; Human Resource Management Division; Assets and Financial Management Division; and the Information and Communication Technology Management Division.

"(d) The Policy and Planning Office which shall be under the Office of the Director-General shall have, at least, a training, advocacy and communications division and shall monitor the performance of the centers for product research and evaluation and standards development.

"(e) The Field Regulatory Operations Office headed by the deputy director-general for field regulatory operations shall include, among others, all the field offices, field or satellite laboratories and the regulatory enforcement units.

"(f) The Legal Services Support Center shall provide legal services to the entire FDA and shall be directly under the Office of the Director-General."

Section 7. Section 6 of Republic Act No. 3720, as amended, is hereby further amended, to read as follows:

"(a) The FDA shall be headed by a director-general, with the rank of undersecretary, who shall be tasked, among others, to determine the needed personnel and to appoint personnel, below the assistant director level in coordination with the Secretary of Health.

"(b) The director-general shall be assisted by two (2) deputy directors-general, one for administration and finance and another for field regulatory operations.

"(c) The director-general and deputy directors-general shall be appointed by the President of the Republic of the Philippines.

"(d) The director-general shall, referably, possess either a university degree in medicine or at least the relevant master's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management. In addition, he/she shall have management experience in his/her field of discipline or profession and in any development, manufacturing, regulatory work or quality assurance of products as covered in this Act.

"(e) The Deputy Director-General for Field Regulatory Operations of the FDA shall, preferably, possess the relevant master's degree in pharmaceutical sciences or allied sciences, or equivalent executive course in any regulatory management. In addition, he/she shall have management experience in his/her field of discipline or

profession and in any development, manufacturing, regulatoly work or quality assurance of products as covered in this Act.

"(f) The Deputy Director-General for Administration and Finance of the FDA shall he a certified public accountant or shall possess a master's degree in accounting, management, economics or any business course, and must have management experience in a position related to his/her field of discipline or profession.

"(g) A person who was previously employed in a regular full-time capacity regardless of its consultative designation at higher management supervisory levels in regulated establishments, including related foundations, shall be disqualified from appointment as director-general and deputy director-general within three (3) years from termination of employment with the said establishment or foundation. All persons who are candidates for appointment as director-general and deputy director-general must disclose all their incomes for the past three (3) years from all establishments regulated by this Act. The director-general and the two (2) deputy directors-gencral shall, upon assumption into office, declare any conflict of interest with any establishment covered by the FDA, including their foundiitions.

"(h) Each center and field office shall be headed by a director director who shall be assisted by an assistant director. These directors shall be appointed by the Secretary of Health.

"(i) The existing directors of the Bureau of Health Devices and Technology (BHDT) and division chiefs of the BFAD shall be given preference for appointment as directors and assistant directors of their respective centers: *Provided*, That if the current officers of the BFAD and the BHDT applying for the above positions lack the required third level civil service eligibility, they will have to comply with the said requirement within three (3) yearn from their appointment, otherwise their appointment shall be revoked immediately."

Section 8. Section 7 of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"The FDA shall review its staffing pattern and position titles subject to the approval of the Secretary of Health."

Section 9. Section 10, subsections (a), (e), (f), (g), (h), (i), (q),(r), (v), and (w) of Republic Act No. 3720, as amended, are hereby further amended, and new subsections (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), (ii), (jj), (kk), (ll), and (mm) are hereby added to read as follows:

"SEC. 10. For the purposes of this Act, the term:

"(a) 'FDA' means the Food and Drug Administration.

"x x x

"(e) 'Food' means any processed substance which is intended for human consumption and includes drink for man, beverages, chewing gum and any substances which have been used as an ingredient in the manufacture, preparation or treatment of food.

"(f) 'Drug' means: (1) articles recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4)articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories.

"(g) 'Device' means medical devices, radiation devices and health-related devices.

"(1) 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention,, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means but which may be assisted in its intended function by such means.

"(2) 'Radiation device' means 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.

"(3) 'Health-related device' means any device not used in health care but has been determined by the FDA to adversely affect the health of the people.

"(h) 'Cosmetics' means any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odor, and/or protecting the body or keeping them in good condition.

"(i) 'Label' means a display of written, printed, or graphic matter upon, the immediate container of any article and a requirement made by or under authority of this Act that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or easily legible through the outside container or wrapper.

"x x x

"(q) 'Director-general' means the head of the FDA.

"(r) 'Distribute' means the delivery or sale of any health product for purposes of distribution in commerce, except that such term does not include the manufacture or retail of such product.

"x x x

"(v) 'Manufacturer', in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formnlating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: *Provided*, That the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

"(w) 'Veterinary drugs' means drugs intended for use for animals including any drug intended for use in animal feeds but not including animal feeds within the contemplation of the implementing rules and regulations.

"(x) 'Assay' is an analysis to determine the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug.

"(y) 'Authorization' means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

"(z) 'Bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(aa) 'Bioequivalence' means the rate and extent of absorption to which the drugs do not show a significant difference from the rate and extent of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses. Bioequivalence shall also refer to the absence of a signiticant difference on the rate and extent-to-which the active ingredient(s) of the sample and reference drug becomes available at the site of drug action when administered under the same molar dose and under similar conditions.

"(bb) 'Distributor/importer/exporter' means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

"(cc) 'Distributor/wholesaler' means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

"(dd) 'Establishment' means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products including the facilities and installations needed for its activities.

"(ee) 'Food/dietary supplement' means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines.

"(ff) '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.

"(gg) 'Household/urban hazardous substance' is:

> "(1) Any substance or mixture of substances intended for individual or limited purposes and which is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat or other means, if such substance or mixture of substances may cause substantial injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children, but shall not include agricultural fertilizer, pesticide, and insecticide, and other economic poisons, radioactive substance, or substances intended for use as fuels, coolants, refrigerants and the like;
>
> "(2) Any substance which the FDA finds to be under the categories enumerated in clause (1) of this paragraph;
>
> "(3) Any toy or other articles intended for use by children which the FDA may determine to pose an electrical, chemical, physical, or thermal hazard; and
>
> "(4) This term shall not apply to food, drugs, cosmetics, devices, or to substances intended for use as fuels when stored in containers and used in the heating, cooking or refrigeration system of a house, but such term shall apply to any article which is not in itself an agricultural pesticide but which is a hazardous substance, as construed in paragraph (1) of this section, by reason of bearing or containing such harmful substances described therein.

"(hh) 'In-vitro diagnostic reagents' are reagents and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae.

"(ii) 'Licensing' means the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

"(jj) 'Misbranding' means, in addition to definitions in existing laws, misinformation or misleading information on the label or other information materials authorized by the FDA. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

"(kk) 'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products.

"(ll) 'Trader' means any establishment which is a registered owner of a health product and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

"(mm) 'Retailer' means any establishment which sells or offers to sell any health product directly to the general public."

Section 10. Section 11, subsections (a), (b), (d), (g), (j),(k) and (l) of Republic Act No. 3720, as amended, are hereby further amended to read as follows:

"SEC. 11. The following acts and the causing thereof are hereby prohibited:

"(a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded.

"(b) The adulteration or misbranding of any health product.

"x x x

"(d) The giving of a guaranty or undertaking referred to in Section twelve (b) hereof which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect, signed by, and containing the name and address of the person or entity from whom he received in good faith the health products or the giving of a guaranty or undertaking referred to in Section twelve (b) which guaranty or undertaking is false.

"x x x

"(g) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to health products if such act is done while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded *Provided*, That a retailer may sell in smaller quantities, subject to guidelines issued by the FDA.

"x x x

"(j) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any health product which, although requiring registration, is not registered. with the FDA pursuant to this Act.

"(k) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, or retail of any drug, device or in-vitro diagnostic reagent; the manufacture, importation, exportation, transfer or distribution of any food, cosmetic or household/urban hazardous substance; or the operation of a radiation or pest control establishment by any natural or juridical person without the license to operate from the FDA required under this Act.

"(l) The sale, offering for sale, importation, exportation, distribution or transfer of any health product beyond its expiration or expiry date, if applicable.

"x x x

"The prohibited acts mentioned herein shall cover all applicable health products."

Section 11. Section 12, subsection (a) of Republic Act No, 3720, as amended, is hereby further amended to read as follows:

"SEC. 12. (a) Any person who violates any of the provisions of Section eleven hereof shall, upon conviction, suffer the penalty of imprisonment ranging from one (1) year but not more than ten (10) years or a fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00), or both, at the discretion of the court: *Provided*, That if the offender is a manufacturer, importer or distributor of any health product, the penalty of at least five (5) years imprisonment but not more than ten (10) years and a fine of at least Five hundred thousand pesos (P500,000.00) but not more than Five million pesos (P5,000,000.00) shall be imposed *Provided*, *further*, That an additional fine of one percent (1%) of the economic value/cost of the violative product or violation, or One thousand pesos (P1,000.00), whichever is higher, shall be imposed for each day of continuing violation: *Provided*, *finally*, That health products found in violation of the provisions of this Act and other relevant laws, rules and regulations may be seized and held in custody pending proceedings, without hearing or court order, when the director-general has reasonable cause to believe from facts found by him/her or an authorized officer or employee of the FDA that such health products may cause injury or prejudice to the consuming public.

"x x x

"Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore shall he penalized.

"Should the offense be committed by a foreign national, he/she shall, in addition to the penalties prescribed, be deported without further proceedings after service of sentence.

"x x x."

Section 12. Section 26, subsections (c) and (d) of Republic Act No. 3720, as amended, are hereby further amended and subsection (g) is hereby added thereto to read as follows:

"x x x

"(c) Hearings authorized or required by this Act shall be conducted by the FDA.

"(d) Upon preliminary findings of the conduct of prohibited act/s, the director-general shall issue the proper notices or orders to the person or persons concerned and such person or persons shall be given an opportunity to be heard before the FDA.

"x x x

"(g) Both criminal and administrative actions may be instituted separately and independent of one another."

Section 13. Section 29-A of Republic Act No. 3720, as amended, is hereby further amended, and new subsections are added to read as follows:

"SEC. 29-A. *Administrative Sanctions*. - Where there is finding of prohibited actions and determination of the persons liable thereto, after notice and hearing, the director-general is empowered to impose one or more of the following administrative penalties:

"(1) Cancellation of any authorization which may have been granted by the FDA, or suspension of the validity thereof for such period of time as the director-general may deem reasonable which shall not exceed one (1) year:

"(2) A fine of not less than Fifty thousand pesos (P50,000.00) but not more than Five hundred thousand pesos (P500,000.00). An additional fine of not more than One thousand pesos (P1,000.00) shall be imposed for each day of continuing violation; and

"(3) Destruction and/or appropriate disposition of the subject health product, and/or closure of the establishment for any violation of this Act, as determined by the director-general."

Section 14. A new Section 30 and a new headnote "Additional Powers and Functions of the Director-General" are hereby added to Republic Act No. 3720, which shall read as follows:

"SEC. 30. The Director-General shall also exercise the following powers:

"(1) To hold in direct or indirect contempt any person who disregards orders or writs he or she issues and impose the appropriate penalties following the same procedures and penalties provided in the Rules of Court;

"(2) To administer oaths and affirmations and issue *subpoena duces tecum* and *subpoena ad testificandum*requiring the production of such books, contracts, correspondence, records, statement of accounts and other documents and/or the attendance and testimony of parties and witnesses as may be material to the investigation conducted by the FDA;

"(3) To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities;

"(4) To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded,

when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines;

"(5) To call on the assistance of any department, office or agency and deputize members of the Philippine National Police or any law enforcement agency for the effective implementation of this Act; and

"(6) To exercise such powers and functions as may be necessary for the effective implementation of this Act."

Section 15. Two new sections shall be added, which shall be the new Sections 31 and 32 of Republic Act No. 3720, as amended, which shall read as follows:

"SEC. 31. The orders, rulings or decisions of the FDA shall become final and executory fifteen (15) days after the receipt of a copy thereof by the party adversely affected unless within that period, an administrative appeal has been perfected. One motion for reconsideration may be filled, which shall suspend the running of the said period."

"SEC. 32. The orders, rulings or decisions of the FDA shall be appealable to the Secretary of Health. An appeal shall be deemed perfected upon filing of the notice of appeal and posting of the corresponding appeal bond.

"An appeal shall not stay the decision appealed from unless an order from the Secretary of Health is issued to stay the execution thereof."

Section 16. Section 30 of Republic Act No. 3720, as amended, shall be renumbered as Section 33, and the subsequent sections shall also be renumbered accordingly.

Section 17. Section 31, Chapter XIII of Republic Act No. 3720, as amended, is hereby further amended to read as follows:

"SEC. 34. *Fees and Other Income*. -

"(a) Upon the sole approval of the Secretary, the authorization and other fees shall annually be determined and reviewed by the FDA and any proposed increase shall be published in two (2) leading newspapers of general circulation.

"(b) There shall be determined and constituted additional fees such as sale of publications and services, assessment fees, fines, penalties, and other fees and charges outside the usual licensing and registration fees, to be known as 'other related regulatory fees'.

"(c) The Director-General of the FDA, upon approval of the Secretary, shall be authorized to promulgate rules and regulations governing the collection of the 'other related regulatory fees'. Upon approval of the Secretary, these fees shall likewise be reviewed periodically and any proposed increase shall be published in two (2) leading newspapers of general circulation."

Section 18. All income that the FDA is allowed to retain under Section 31 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 shall, any provision of law to the contrary notwithstanding, be deposited in an authorized government depository bank as a special regulatory fund. Any interest earned by such fund shall form part of the retained income. Such fund shall be used primarily for the acquisition of office and laboratory space, human resource development and expansion, purchase of laboratory equipment and motor vehicles, the upgrading of its current facilities and equipment and maintenance, other operating expenses ofthe central office laboratory divisions and satellite laboratories in Davao, Cebu and other testing laboratories, in case the above laboratories will be increased, and other activities or services of the agency in the performance of its mandate.

The fund shall be allowed to accept grants, donations and all other endowments from local and external sources in accordance with pertinent laws, rules and regulations.

The retention, use and application of this fund shall not be delayed, amended, altered or modified, or affected in any way by an order or directive from any executive office, but will be subject only to the general accounting rules and guidelines by the Commission on Audit (COA). The primary purpose of the fund as herein stated shall prevail over any other purpose that may be pursued by the FDA on its own initiative or through an order or directive by any higher office. The FDA shall submit to the Secretary of Health, the Secretary of Budget and Management and the Congressional Oversight Committee, created under Section 23 of this Act, a report on how the funds were utilized, including its accomplishments.

There shall also be established a legal fund out of the interest earned from the retained income for use in case of legal actions against the officials and employees of the FDA in the course of the exercise of their official functions and duties.

Section 19. The FDA shall establish a Regulatory Enforcement Unit (REU) for a period not exceeding five (5) years from the effectivity of this Act. It shall be composed of at least five (5) qualified personnel in every region who shall be directly under the control and supervision of the Deputy Director-General for Field Regulatory Operations and shall be administratively supported by the field offices. They shall:

(a) Bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents;

(b) Serve and execute rulings, orders, and decisions of the Director-General of the FDA; and

(c) Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under this Act and related laws concerning the regulation of health products.

All law enforcement agents shall undergo the appropriate training to equip them with the necessary skills needed for this purpose. Their authority and functions shall be strictly limited to the implementation of the FDA's regulatory functions.

All regional regulatory enforcement units shall be headed by a lawyer who is at least thirty (30) years old but not older than fifty (50), an Integrated Bar of the Philippines (IBP) member of good standing, and shall have a rank of a Division Director; and an assistant who must be at the very least a law graduate who shall have a rank of an Assistant Division Director.

Section 20. A new chapter XIV and three new sections, Sections 35, 36, and 37 shall be introduced, which shall read as follows:

"CHAPTER XIV
"TESTING LABORATORIES AND FIELD OFFICES

"SEC. 35. The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, calibrate, assay and examine samples of health products. For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have the necessary and appropriate state-of-the-art laboratory equipment and personnel complement. The main testing laboratories at the central office shall be maintained and shall serve as a support unit to the centers for product research and evaluation and standards development and shall serve as testing centers that would include assay and the conduct, supervision, oversight and/or audit of bioequivalence and bioavailability test/researches, among others. The existing laboratories in Cebu and Davao will be upgraded and transformed as quality assurance laboratories, while another one will be established in Subic, Zambales.

"The testing laboratories may be increased by the director-general, upon approval of the Secretary. Moreover, the director-general, upon approval of the Secretary, may call upon other government and private testing laboratories to conduct testing, calibration, assay and examination of samples of health products: *Provided*, That the private testing laboratories are accredited by the Philippine Accreditation Office (PAO) of the Department of Trade and industry (DTI) and the DOH."

"SEC. 36. The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA's sole control and supervision. The regional field office shall also assume primary jurisdiction in the collection of samples of food, drugs, devices and cosmetics being imported or offered for import at a port of entry other than Manila in his/her assigned region and where it appears that said items or products satisfy any of the conditions as provided for in Section 33(a) of Republic Act No. 3720, as amended, without prejudice to the exercise of the powers of the director-general provided under Sections 13 and 14 of this Act in the exercise of the agency's regulatory functions. The field offices shall be comprised of the following: (a) licensing, inspection and compliance division, which shall have charge of the inspection of food, drugs and cosmetic establishments engaged in their manufacture, importation, distribution, and sale; (b) satellite laboratory division; and (c) administrative division."

"SEC. 37. The FDA, with the approval of the Secretary, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards. There shall be created additional plantilla positions to augment the human resource complement of the FDA, subject to existing rules and regulations."

Section 21. *Appropriations*. - The appropriations for the BFAD and the BHDT included in the budget of the DOH under the current General Appropriations Act shall be used to carry out the implementation of this Act. The appropriation may be augmented by the income which the agency is authorized to use under this Act. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

Section 22. *Implementing Rules and Regulatiorts.* - The DOH shall promulgate, in consultation with the FDA, the implementing rules and regulations of this Act within one hundred twenty (120) days after the passage of this Act.

Section 23. *Congressional Oversight Committee.* - A Congressional Oversight Committee (COC) is hereby created composed of the Chairpersons of the Committees on Health and Appropriations of the House of Representatives and two (2) Members to be appointed by the Speaker, the Chairpersons of the Committees on Health and Finance of the Senate and two (2) Members to he appointed by the President of the Senate, to oversee the implementation of this Act for a period of five (5) years and to review the accomplishments and the utilization of income of the FDA. The secretariat of the COC shall be drawn from the existing personnel of the committees comprising the COC.

Section 24. *Transitory Provisions*. - The BFAD Director and Deputy Director shall serve as FDA Director-General and Deputy Director-General for Field Regulatory Operations, respectively. The current officials and employees of the BFAD shall be transferred as far as practicable to the appropriate unit in the FDA as determined by the Director-General. The current officials and employees of the BHDT shall be transferred to the Center for Device Regulation, Radiation Health, and Research. The current regional food and drug regulatory officers and regional health physicists under the Centers for Health Development of the DOH shall be transferred as far as practicable to the appropriate unit in the FDA as determined by the Director-General. There shall be no demotion in ranks and positions and no diminution in salaries. benefits, allowances and emoluments of all BFAD, BHDT and indicated Center for Health and Development (CHD) personnel transferred to the FDA. All positions, powers, functions and duties together with the facilities, equipment, supplies, records, files, appropriations, and funds for these bureaus and the indicated CHD personnel shall be transferred to the FDA.

Section 25. *Coverage*. - This Act shall govern all health products: *Provided*, That nothing in this Act shall be deemed to modify the sole and exclusive jurisdiction of other specialized agencies and special laws only insofar as the acts covered by these specialized agencies and laws, including, but not limited to, those covered by Republic Act No. 9211, Executive Order No. 245, Executive Order No. 18, and Presidential Decree No. 1468.

Section 26. *Separability Clause*. - If any part, section or provision of this Act shall be declared invalid or unconstitutional, other provisions or parts thereof which are not affected thereby shall remain in full force and effect.

Section 27. *Repealing Clause*. - Laws or part of laws, executive orders, circulars, regulations and memoranda inconsistent with this Act are hereby repealed or amended accordingly.

Section 28. *Effectivity Clause*. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) newspapers of generhl circulation.

Approved,

(Sgd.) **PROSPERO C. NOGRALES**
Speaker of the House of Representatives

(Sgd.) **JUAN PONCE ENRILE**
President of the Senate

This Act which is a consolidation of Senate Bill No. 2645 and House Bill No. 3293 was finally passed by the Senate and the House of Representatives on June 3, 2009.

(Sgd.) **MARILYN B. BARUA-YAP**
Secretary General
House of Represenatives

(Sgd.) **EMMA LIRIO-REYES**
Secretary of Senate

Approved: **AUG 18 2009**

(Sgd.) **GLORIA MACAPAGAL-ARROYO**
President of the Philippines