REPUBLIC OF THE PHILIPPINES
CONGRESS OF THE PHILIPPINES
METRO MANILA

SECOND REGULAR SESSION

Begun and held in Metro Manila, on Monday, the twenty-second day of July, nineteen hundred and ninety-six

[REPUBLIC ACT NO. 8203]

AN ACT OF PROHIBITING COUNTERFEIT DRUGS, PROVIDING PENALTIES FOR VIOLATIONS AND APPROPRIATING FUNDS THEREFOR

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

SECTION 1. ***Title*** – This Act shall be known as the "Special Law on Counterfeit Drugs."

SECTION 2. ***Declaration of Policy*** - It is hereby the policy of the State to protect and promote the right to health of the people and instill health consciousness among them as provided in Section 15 Article 11 of the Constitution.

It is also further declared the policy of the State that in order to safeguard the health of the people, the State shall provide for their protection against counterfeit drugs.

SECTION 3. ***Definition of Terms*** – For purposes of this Act, the terms:

(a) Drugs shall refer to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in man or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia – National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippines National Drug Formulary, British Pharmacopoeia, any National Compendium or any supplement to any of them;

(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) any article other than food intended to affect the structure or any function of the body of man or animals;

(4) any article intended for use as a component of any articles specified in clauses (1), (2), (3) not including devices or their components, parts, or accessories; and

(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

(a) recognized in the Philippine National Drug Formulary; (b) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defect in man; (c) other than food, intended to affect the structure or any function of the body of man; (d) in finished or ready-to-use dosage form; and (e) intended for use as a component of any of the articles specified in clauses (a), (b), (c) and (d).

(b) Counterfeit drug/medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:

1) the drug itself or the container or labeling thereof or any part of such drug, container or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Technology Transfer (BPTTT) in the name of another natural or juridical person;

2) a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;

3) an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records;

4) a drug which contains no amount of or a different active ingredient or less than eighty percent (80%) of the active ingredient it purports to possess as distinguished from an adulterated drug including reduction or loss or efficacy due to expiration.

(c) Brokering shall refer to any act of facilitating the disposal or sale or counterfeit drugs, including acts of agency.

(d) Bureau shall refer to the Bureau of Food and Drugs (BFAD) of the Department of Health (DOH).

(e) Department shall refer to the Department of Health

(f) Business establishment shall refer to any entity, whether a single proprietorship, partnership, or corporation engaged in or doing business in the Philippines.

(g) Owner shall refer to a person or group of persons who is the registered owner of a license to operate a business or business undertaking in the Philippines or the branch manager or operator, licensee, franchisee, or any person acting on behalf of he corporate entity.

(h) Residence shall refer to a private dwelling or abode where a person lives, either as owner or lessee, or usurfructuary including, for purposes of this Act, its yard, garage, storage rooms or premises.

SECTION 4 ***Prohibited Acts.*** – The following acts are declared unlawful and therefore prohibited;

a) The manufacture, sale, or offering for sale, donation, distribution, trafficking, brokering, exportation, or importation or possession of counterfeit drugs as defined in Section 3 hereof not otherwise covered by Republic Act No. 3720, as amended. The presence or availability of such counterfeit drugs within the premises of any entity engaged in the sale, manufacture or distribution of drugs and/or pharmaceutical products or in a private residence, or in public or private

vehicle, or in the premises not covered by a valid license to operate from the Bureau, shall constitute a prima facie evidence of violation of this Act: Provided, however, That this presumption shall not apply to the legitimate owners of trademarks, trade names or other identifying marks, or the legitimate or authorized representatives or agents of such owners who have in their possession counterfeit drugs which bear the trademarks, trade names or marks if they can show the sales invoices or official receipts evidencing their purchase from a drugstore, manufacturer or distributor suspected by them of dealing in counterfeit drugs involving the trademarks, trade names and other similar identifying marks registered in their names: Provided, further, That such counterfeit products shall be reported and immediately turned over to the Bureau: Provided, finally, That compliance with the preceding provision shall be made within a reasonable period from the date of purchase of such counterfeit drugs as indicated in the sales invoice, official receipt, or other similar documents abovementioned to the time the counterfeit drugs are reported and turned over to the Bureau;

b) Possession of any such counterfeit drugs. However, any person found in possession of counterfeit drugs, in violation of this subsection, shall be exempted from liability under the provisions of this Act after:

1) presentation of sales invoices, official receipts or other legally acceptable documents evidencing his purchase thereof from a drugstore, distributor, manufacturer, hospital pharmacy or dispensary; or any other person or place duly licensed to sell and/or dispense drugs or medicines and indicating therein the batch and lot numbers, as well as the expiry dates of such drugs; or

2) presentation of certificates and other documents evidencing the importation or exportation of the counterfeit drugs found in his possession as required by existing laws, including those documents required in the preceding paragraph covering the commercial transactions involving counterfeit drugs.

In both cases, the subject counterfeit drugs must not on their face appear to be as such, or do not bear any marking or any patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person that such drugs are counterfeit. Furthermore, the amount or volume of counterfeit drugs held is such that it does not negate or is inconsistent with the averment that the same are for personal use, notwithstanding the presentation by the possessor of medical records and other similar documents accompanying and justifying the use of such drugs;

c) Forging, counterfeiting, simulating or falsely representing, or without proper authority, using any mark, stamp, tag, label or other identification mark or device authorized or required by Republic Act No. 3720, as amended, and/or the regulations promulgated under this Act;

d) Photocopying, duplicating, altering, printing, transferring, obliterating or removing the approved label or any part thereof, lawfully belonging to another person, for the purpose of using such label or a part thereof on any counterfeit drug: Provided, That if the person who committed any of the acts enumerated in this paragraph and the person who used the labels produced thereby are not one and the same person and the former had knowledge of the purpose for which the labels are intended, the former shall also be liable under this Act notwithstanding the failure of the latter to achieve the intended purposes; and

e) Making, selling, or concealing any punch, dye, plate or any other equipment or instrument designed to print, imprint or reproduce the trademark, trade name or other identifying mark of another registered producer or any likeness thereof, upon

any drug product or device or its container or label without authority from the legitimate owners of the trademark or trade name.

SECTION 5. ***Parties Liable*** - The following persons shall be liable for violation(s) of this Act:

a) the manufacturer, exporter or importer of the counterfeit drugs and their agents: Provided, That the agents shall be liable only upon proof of actual or constructive knowledge that the drugs are counterfeit;

b) the seller, distributor, trafficker, broker or donor and their agents, upon proof of actual or constructive knowledge that the drugs sold, distributed, offered or donated are counterfeit drugs;

c) the possessor of counterfeit drugs as provided in Section 4 (b) hereof;

d) the manager, operator or lessee of the laboratory or laboratory facilities used in the manufacture of counterfeit drugs;

e) the owner, proprietor, administrator or manager of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit drug is found who induces, causes or allows the commission of any act herein prohibited;

f) the registered pharmacist of the outlet where the counterfeit drug is sold or found, who sells or dispenses such drug to a third party and who has actual or constructive knowledge that said drug is counterfeit; and

g) should the offense be committed by a juridical person the president, general manager, the managing partner, chief operating officer or the person who directly induces, causes or knowingly allows the commission of the offense shall be penalized.

SECTION 6. ***Administrative Proceedings.-*** The Bureau is hereby further authorized to undertake the following administrative actions:

a) upon verified information on the existence of suspected counterfeit drugs in the possession of any manufacturer, seller or distributor, the duly authorized officers of the bureau or any officer deputized by the Bureau for the purpose shall segregate, seal and after having obtained a valid search warrant from a competent court, seize such counterfeit drugs and take them into custody: Provided, That in case the suspected counterfeit drugs are found in a private residence, as defined in Section 3 of this Act or in other premises not covered by a valid license to operate issued by the Bureau, the duly authorized officer of the Bureau or deputized officer thereof shall secure a search warrant for the purpose of seizing and taking into custody such suspected counterfeit drugs;

b) if, after the appropriate examination of the samples by the Bureau, the seized drugs are determined or found to be counterfeit, the Bureau shall, within (15) days from their seizure, issue an order directing the preventive closure of the business establishment for a period not exceeding thirty (30) days. Thereafter, administrative proceedings shall be initiated by the Bureau against the parties concerned where they shall have the opportunity to be heard and present evidence on their behalf; and

c) to ensure the effective enforcement of the foregoing, the Bureau may enlist the assistance of the national or local law enforcement agencies.

SECTION 7. ***Administrative Sanctions*** – Upon finding that the drugs examined are counterfeit and the determination of the parties liable thereof, the Bureau shall impose any or all of the following sanctions:

a) permanent closure of the establishment concerned and the revocation of its license to business;

b) a fine of not less than One hundred thousand pesos (P100,000) but not more than Five hundred thousand pesos (P500,000);

c) upon order of the Court, forfeiture, confiscation, and destruction of products found to be counterfeited and the equipment, instruments, and other articles used in violation of this Act;

d) filing of an appropriate proceedings against the registered pharmacist with the Professional Regulations Commission for cancellation of professional license;

e) filing of criminal charges against the violator (s), which can be instituted independently from the administrative case: Provided, That the dismissal of the criminal case shall not lift the closure order, except when it is a dismissal on the merits or for lack of basis: Provided, further, That the withdrawal of the private criminal complaint shall not be a ground for the dismissal of the administrative proceedings; and

f) permanent disqualification of the person concerned, whether natural or juridical, from owning or operating an establishment engaged in any business activity under the supervision of the Bureau.

SECTION 8. ***Penalties***. – The commission of any of the acts prohibited under Sections 4 and 6 of this Act shall be punished by:

a) imprisonment of not less than six (6) months and one (1) day; but not more than six (6) years for more possession of counterfeit drugs as provided for in Section 4(b) hereof; or

b) imprisonment of six (6) years and one (1) day, but not more than ten (10) years or a fine of not less than One hundred thousand pesos (P100,000) but not more than Five hundred thousand pesos (P500,000) or both such imprisonment and fine at the discretion of the court in any other case mentioned in Section 4 hereof; or

c) imprisonment of not less than six (6) months and one (1) day, but not more than two (2) years and four (4) months if the counterfeit drug is intended for animals; or

d) imprisonment of not less than six (6) years and one (1) day but not more than ten (10) years for any manufacturer, seller or distributor who shall conceal, substitute, dispose or destroy any drug as may have been segregated and sealed by the Bureau or who shall break, alter or tamper any mark or seal used by the Bureau to identify those segregated drugs as provided for under Section 6(a) of this Act. Any other person who breaks, alters or tampers any mark or seal used by the Bureau to identify the segregated drugs shall suffer the penalty of not less than six (6) months and one (1) day, but not more than six (6) years imprisonment; or

e) if, as a result of the use of the drug found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, a punishment of imprisonment from twelve (12 years to fifteen (15) years and a fine ranging from One hundred thousand pesos (P100,000) to Five hundred thousand pesos (P500,000) shall be meted out; or

f) should a counterfeit drug be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit drug, the penalty of life imprisonment and a fine of Five hundred thousand pesos (P500,000) to Five million pesos (P5,000,000) shall be imposed.

In case any act prohibited in Section 4 hereof is also punishable under other laws, the offender shall, if warranted by the evidence, be prosecuted under the law prescribing the highest penalty.

SECTION 9. ***Appropriations*** – The amount necessary to carry out the provisions of this Act shall be included in the General Appropriations Act for the year following its enactment and every year thereafter.

SECTION 10. ***Implementation*** – The Bureau of Food and Drugs of the Department of Health is hereby authorized to administer and supervise the implementation of this Act.

SECTION 11. ***Implementing Rules and Regulations.*** – Within ninety (90) days from the approval of this Act, the Bureau of Food and Drugs, in consultation with the Department of Health, shall promulgate the rules and regulations implementing the provisions of this Act. The implementing rules and regulations issued pursuant to this section shall take effect thirty (30) days after its publication in two (2) national newspapers of general circulation.

SECTION 12. ***Separability Clause*** – If, for any reason, any portion or provision of this Act is subsequently declared unconstitutional or invalid, such declaration shall not nullify the other portions or provisions hereof.

SECTION 13. ***Repealing Clause.*** – all laws, decrees, executive or administrative orders, rules or regulations inconsistent with the provisions of this Act are hereby or modified accordingly.

SECTION 14. ***Effectivity***. – This Act shall take effect fifteen (15) days after its publication in at least two (2) national newspapers of general circulation.

Approved,

(Sgd) JOSE DE VENECIA, JR.
Speaker of the House
of Representatives

(Sgd) NEPTALI A. GONZALES
President of the Senate

This Act, which is a consolidation of Senate Bill NO. 1284 and House Bill No. 5666 was finally passed by the Senate and the House of Representatives on August 27, 1996 and August 22, 1996, respectively.

(Sgd) ROBERTO P. NAZARENO
Secretary General
House of Representatives

(Sgd) HEZEL P. GACUTAN
Secretary of the Senate

Approved: September 4, 1996

(Sgd) FIDEL V. RAMOS
President of the Philippines