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

RULES AND REGULATIONS IMPLEMENTING
REPUBLIC ACT NO. 8203 OTHERWISE KNOWN AS
THE SPECIAL LAW ON COUNTERFEIT DRUGS

AUTHORITY

Pursuant to Section 11 of Republic Act No. 8203 otherwise known as the Special Law on Counterfeit Drugs, the following rules and regulations are hereby promulgated in consultation with the Secretary of Health.

RULE I
INTERPRETATION AND DEFINITION OF TERMS

Section 1. ***Short Title***. These rules and regulations shall be cited as "IRR of R.A. 8203."

Section 2. ***Construction.*** The words and phrases used in these rules shall be interpreted to give meaning to the provisions of R.A. 8203 in order to safeguard the health of the people and to protect them from counterfeit drugs.

Section 3. ***Definition of Terms.*** In addition to the terms defined by Section 3 of R.A. 8203, and for purposes of these regulations, the term --

(a) ***"Bureau or BFAD"*** shall refer to the Bureau of Food and Drugs
(b) ***"Constructive Knowledge"*** as here applied shall mean, that by exercise of reasonable care, one would have known the fact or suspect that the drug product he or she has sold or in possession of is counterfeit, such as but not limited to the knowledge that the drug was not covered by any sales invoice or evidence of delivery of purchase from a BFAD license drug establishment.
(c) ***"FDRO"*** shall mean Food and Drug Regulation Officer
(d) ***"LICD"*** shall mean Legal, Information and Compliance Division of the BFAD
(e) ***"Life saving drugs"*** shall refer to drug products indicated for life threatening condition(s)
(f) ***"LSD"*** shall mean Laboratory Services Division of BFAD
(g) ***"PSD"*** shall mean Product Services Division of BFAD
(h) ***"Unregistered imported drug product"*** as distinguished from counterfeit drug defined under Section 3 of R.A., shall refer to unregistered imported drug product without a registered counterpart brand in the Philippines. If the unregistered imported drug product has a registered counterpart brand in the Philippines, their product shall be considered counterfeit.

RULE II
PROHIBITED ACTS

Section 1. ***Prohibited Acts.*** The acts prohibited or declared unlawful under Section 4 of R.A. 8203 are adopted as the same acts that are prohibited by these rules and therefore punishable by the administrative sanctions herein prescribed.

Section 2. ***Parties Liable.*** The parties who are liable under Section of R.A. 8203 are likewise made liable under these rules.

RULE III
MONITORING OF COUNTERFEIT DRUGS

Section 1. ***Procedure of Monitoring Counterfeit Drugs in the Market***

(a) The Food and Drugs Regulation Officers (FDROs) in the course of their inspection of a factory, warehouse, establishment or vehicle, finished or raw materials, containers and

labeling therein upon the authority conferred by Section 27 of R.A. 3720 as amended, shall further determine during such inspection, whether the drug products therein found are counterfeit or not. For the effective implementation of R.A. 8203, the said inspection shall be without prior notice in any place within the Philippines to prevent the parties liable from concealing them and avoiding inspection.

(b) If upon such inspection, the FDRO shall suspect certain stocks as counterfeit drugs, the FDRO shall conduct an inventory, segregate and seal the suspected stocks, and collect samples for examination as to the drug products' geniuneness and authenticity.

(c) The FDRO shall require the owner or the representative of the inspected establishment or outlet to produce the sales invoice, delivery receipts or documents covering the suspected counterfeit drugs. The FDRO shall only acknowledge and recognize invoices or documents that have been issued by a BFAD licensed manufacturer, trader, distributor, wholesaler or importer with the lot number and expiry date of the drug product(s) indicated therein.

(d) Immediately upon return to his/her office, the FDRO concerned shall submit the samples to either the LSD or PSD for their examination or evaluation. The examination or evaluation shall be for the purpose of determining the authenticity and/or geniuneness of the said samples.

Section 2. ***Duration In the Conduct of Examination.*** The BFAD shall have twenty (20) working days to determine the genuineness and authenticity of the product.

Section 3. ***When There Is No Need For Laboratory Testing.*** When the geniuneness of the product can be determined by the mere physical examination of the product or the labeling thereof, the PSD shall conduct the examination or evaluation of the same. The result of the physical examination shall be reduced into a certification of findings.

The Regulation Division I may also require the registered brand-owner of the suspected counterfeit drug to certify whether or not the suspected drug product has been manufactured, imported and/or distributed by them; or whether they own the Lot Number and Expiry Date of the same suspected drug product. The certification issued by the registered brand-owner shall be supported by the batch, production and distribution records. However, the brand-owner's certification shall be validated by the PSD for evidentiary purposes.

Section 4. ***When To Refer To LICD For Investigation.*** When the result of examination shall confirm the suspicion of the FDRO that in fact the drug product is counterfeit, the LSD or PSD shall forward the result of examination to the LICD for a motu proprio investigation. Otherwise, the result of the examination shall be released to the Regulation Division concerned.

Section 5. ***When The Product Is Found Not Counterfeit.*** When the result of the examination reveals that the sample collected is genuine, the PSD or LSD shall forward the report of examination or evaluation to the FDRO through his/her division chief.

If the sealed and segregated products are within the Metro Manila area, the Regulation Division concerned shall, within sixteen (16) working hours from receipt of such report, notify the outlet or the communication available. However, only a FDRO can unseal the suspected product before it can be released for sale or distribution to legitimate commerce.

When the segregated and sealed products are located outside the Metro Manila area, the Regulation Division concerned shall send a notice to release the products to the Food and Drug Section having territorial jurisdiction over the same through the Regional Director within sixteen (16) working hours from receipt of the notice. The FDRO assigned in the said province shall, within sixteen 916) hours from receipt of the notice, unseal the suspected drugs for distribution to legitimate commerce

Section 6. ***Accreditation of Complaint Desk.*** Upon application by an interested pharmaceutical association. BFAD shall accredit complaint desks that may be established

by any pharmaceutical organization or association. The desk shall receive and refer verifiable letter of complaint or information from any of its members about counterfeit drug products. Any letter of complaint or information referred to BFAD by such complaint desk shall be processed in accordance with Section 2 of Rule IV hereof.

Section 7. ***Possession Of Counterfeit Drugs by Owners Of Trademarks, Trade Names Or Other Identifying Marks; When to Report.*** Owners of trademarks, trade names or other identifying marks, or their authorized agents who have in their possession counterfeit drug product involving their own trademark, trade name or other identifying marks, shall report in writing and turn over the said counterfeit drugs to the BFAD within ten (10) days from the time of purchase or acquisition of such drugs as indicated in the sale invoices or official receipt or other similar documents. The sales invoice, official receipts or other similar documents shall be attached to the said report on counterfeit drugs. Failure to comply with this section will give rise to the presumption of violation as provided under Section 4(a) of R.A. 8203.

RULE IV
PROCEDURE IN THE FILING OF ADMINISTRATIVE COMPLAINT

Section 1. ***Where to File the Complaint.*** Any person may file a complaint whether in an affidavit or letter form with the BFAD LIC or in any BFAD Accredited Complaint Desk as provided for in Section 8 Rule II of this Order.

Section 2. ***Complaint Filed By A Registered Brand Owner.*** A drug establishment or a registered brand owner may file an administrative action against any person or establishment for any acts in violation of R.A. 8203 in the form of an affidavit of complaint.

Section 3. ***Contents of the Complaint Affidavit.*** The affidavit of complaint of the registered brand owner shall state--

(a) name of the product, the lot numbers and expiry date of the products he shall allege as counterfeit;
(b) name and address of the person and/or drug establishment or company he shall name as party-respondent;
(c) specific acts that he shall allege as having been committed by the party-respondent;
(d) remedy or relief or action he shall intend BFAD to take.

The affidavit of complaint shall be accompanied by samples of counterfeit drug products duly marked for identification purposes.

Section 4. ***Complaint Filed By A Consumer, A Physician Prescriber and Other Interested Party.*** A consumer, physician-prescriber or other interested party other than the registered brand owner may file a letter of complaint or information about a suspected counterfeit drug product. His letter shall state--

(a) the name of the suspected product;
(b) the source or the name and address of the person from whom he/she acquired the said suspected drug product;
(c) the mode of his acquisition, and
(d) the reason or fact giving rise to the suspicion that the drug product is counterfeit.

Section 5. ***When The Consumer, Physician Prescriber Or Interested Party May File An Affidavit Of Complaint And Not a Letter of Complaint.*** When the consumer, physician-prescriber or the interested party is in possession of evidence to prove that the product is counterfeit and an act in violation of R.A. 8203 has been committed, he/she shall instead file an affidavit of complaint stating --

(a) the name and address of the person who has committed the act of violation of R.A. 8203; and
(b) the specific acts committed.

He/she shall submit and offer the evidence in his/her possession specifically including the sample of the counterfeit drug product or the container of such product he shall allege as counterfeit. Such an affidavit of complaint shall be processed in accordance with Section 3 of the Rule IV hereof.

RULE V
ADMINISTRATIVE PROCEEDINGS

Section 1. ***When Initiated by BFAD FDROs.*** When the administrative action is initiated by FDRO, the FDRO shall submit a report of violation to the LICD.

(a) Upon receipt of the report of violation and when such report is found proper in form and substance, the LICD shall immediately prepare the formal charge in the form of a memorandum of evidence. The memorandum of evidence shall contain a statement giving the party-respondent fifteen (15) days within which to file his position paper and submit evidence contrary to that which was found, or justifying the acts in violation of R.A. 8203, failing in which, the case will considered submitted for resolution based upon the evidence found and presented to him in the same memorandum of evidence.
(b) If the party-respondent is a drug establishment, outlet or a business establishment, the memorandum of evidence shall be accompanied by a preventive closure order for thirty (30) days from receipt of the order.
(c) If the position paper filed by the respondent shall raise no factual issue that necessitates a trial, the case will be considered submitted for resolution.
(d) If the position paper will raise factual issues necessitating a trial, or the respondent moves for a hearing to confront the witnesses upon which the memorandum of evidence was instituted, a hearing will be conducted.
(e) In the hearing, upon motion of the Respondent, the witnesses upon which the memorandum of evidence had been issued will be called to affirm the documentary evidence and their reports, if any. The party-respondent shall be given the opportunity to confront or cross-examine the said witnesses.
(f) After such affirmation and cross-examination, the party-respondent shall be given another ten (10) days to supplement his position paper or to manifest his intention to present evidence in support of his position paper, if he shall so intend.

In the case the part-respondent manifests hi intention to present evidence in support of his position paper, the continuation of the hearing shall be conducted. Otherwise, the case shall be considered submitted for resolution based on evidence on record.

The administrative proceedings shall be completed and terminated within thirty (30)-day period; otherwise, if such proceedings cannot be completed within the thirty (30)-day period from notice, an order lifting the preventive closure shall be issued without prejudice to the resolution of the administrative case.

Section 2. Procedure ***When A Complaint Is Based On A Letter Of Complaint Or Information***.

(a) Upon receipt of the letter of complaint or information about a suspected counterfeit drug, and upon a preliminary finding that there is sufficient basis to conduct an investigation, the letter of complaint or information will be assigned to an FDRO for verification.
(b) If the information is verified that in fact the drug product is counterfeit and that a person, a drug outlet, or business establishment or drug establishment has committed acts in violation of R.A. 8203, a memodrandum of evidence shall be

issued and the administrative proceedings provided for in Section 1 hereof shall be instituted.

Section 3. ***Procedure When A Complaint is Initiated By a Drug Establishment Or Registered Brand Owner***.

(a) Upon receipt of the complaint and a finding that the complaint is proper in form and substance, the party-respondent shall be summoned to answer within fifteen (15) days from receipt thereof.
(b) The party-respondent shall file an answer and not a motion to dismiss except when the subject matter of complaint is not within the administrative jurisdiction of the BFAD.
(c) The hearing of the case shall be summary in nature and that direct testimonies of the witnesses shall be reduced to an affidavit which shall be submitted within three (3) days before the date of hearing.

Section 4. ***Decision***. Administrative cases under R.A. 8203 and these implementing rules and regulations shall be decided by the Director of BFAD within thirty (3) days from the date it shall be deemed submitted for decision.

Section 5. ***Finality of Decisions/Resolutions.*** Decisions and resolutions shall be final and executory after the lapse of fifteen (15) days from receipt of parties or from notice.

RULE VI
APPEAL

Section 1. ***Motion For Reconsideration; When And When Not Allowed.*** No motion for reconsideration from an interlocutory order shall be allowed. Only one motion for reconsideration from the final resolution or decision shall be allowed and only upon the grounds that --

(a) the resolution is not supported by substantial evidence; and
(b) the conduct of the administrative investigation is attended with irregularity.

Section 2. ***Appeal; When.*** The aggrieved party may appeal the decision of the BFAD Director within fifteen (15) days from receipt thereof to the Secretary of Health.

Section 3. ***Grounds For Appeal.*** No appeal shall be given due course on the following grounds --

(a) Abuse of discretion;
(b) Decision is not supported by substantial evidence; or
(c) Irregularity in the conduct of investigation.

Section 4. ***How Made.*** A party who intends to appeal the decision of the BFAD Director shall file a notice of appeal with the BFAD. The BFAD shall forward the records of the case to the Office of the Secretary within fifteen (15) days from receipt of the notice of appeal.

Section 5. ***Execution Pending Appeal.*** The appeal when filed by a respondent shall not stay the execution of the decision, unless a bond in the amount of One Hundred Thousand Pesos (PHP 100,000.00), which is the minimum administrative fine imposable, is posted.

RULE VII
ADMINISTRATIVE SANCTIONS

Section 1. ***Minimum Penalty.*** An administrative fine of not less than of One Hundred Thousand Pesos (PHP 100,000.00) but not more than of Five Hundred Thousand Pesos (PHP 500,000.00) shall be the minimum administrative penalty.

Section 2.. *Medium Penalty.* An administrative fine of not less than of Three Hundred Thousand Pesos (PHP 300,000.00) but not more than of Five Hundred Thousand Pesos (PHP 500,000.00) and permanent closure of establishment as well as the revocation of its license to do business shall be the medium administrative penalty

Section 3. *Maximum Penalty.* An administrative fine of not less than of Three Hundred Thousand Pesos (PHP 300,000.00) but not more than of Five Hundred Thousand Pesos (PHP 500,000.00) and permanent closure of establishment concerned as well as the revocation of its license to do business shall be the maximum administrative penalty

Section 4. *Accessory Penalties.*

(a) Upon order of the court, all administrative sanctions shall be accompanied by forfeiture, confiscation and destruction of product found to be counterfeit and the equipment, instrument and other articles used in violation of R.A. 8203
(b) 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 shall be imposed together with the maximum administrative penalty.

Section 5. *Proceedings Against the Registration of a Pharmacist.* If the offense shall be committed with the actual or constructive knowledge of the registered pharmacist, the administrative sanction that shall be imposed shall be accompanied by the filing of certificate of violation for the appropriate proceeding against said pharmacist with the Professional Regulation Commission to cancel her/his professional license.

Section 6. *When to File Criminal Charges.* Criminal charges shall be filed against the party liable when the evidence found by BFAD is considered sufficient to establish a probable cause and the drug products involved are life saving or if the drug products are not life saving, the volume or number of the drug products subject to the case will manifest the criminal intent to the party liable to introduce into commerce counterfeit drug products. This, however, shall not preclude any interested party from initiating a criminal action against the party liable independent of BFAD.

Section 7. ***When the Minimum Penalty Shall be Applied.*** The minimum administrative penalty shall be imposed when the counterfeit drug products subject of the case are not life saving drugs and the volume of the said products is not worth more than (PHP 100,000.00); or the number of drug product subject of the case it not more than three brands or generic products.

Section 8. *When the Medium Penalty Shall be Imposed.* The medium administrative penalty shall be imposed when the counterfeit drug products subject of the case are not life saving drugs and the volume of the said products is not worth (PHP 100,000.00) but not exceeding One Million Pesos (PHP 1,000,000.00) or the number of counterfeit drug products is more than three brands or generic products.

Section 9. *When the Maximum Penalty Shall be Imposed.* The maximum administrative penalty shall be imposed when the counterfeit drug products are life saving drugs regardless of the volume; or the volume of the counterfeit drug products is worth more than One Million Pesos (PHP 1,000,000.00)

RULE VIII
FINAL PROVISIONS

Section 1. *Separability* If, for any reason, any part or provision of these rules and regulations shall be held to be unconstitutional or invalid, other parts or provision hereof which are not affected thereby shall continue to be in full force and affect.

Section 2. ***Prospectivity***. The administrative sanctions herein imposed shall not apply to acts committed prior to October 26, 1996 or the effective of the law R.A. 8203.

Section 3. *Amendments*. These rules and regulations may be amended, modified or supplemented when effective implementation and enforcement of R.A. 8203 would require.

Section 4. *Effectivity*. This Order shall take effect thirty days after its publication in two (2) newspapers of general circulation.

(Sgd) QUINTIN L. KINTANAR, M.D., Ph.D., CESO I
Director

In consultation with the Department of Health:

(Sgd) CARMENCITA NORIEGA-REODICA, MD, MPH., CESO II
Secretary of Health

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