REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
D.O.H. Compound
Alabang, Muntinlupa, Metro Manila

Manila Standard
12/4/96 P. 12

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

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 RA 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. No. 8203, and for purposes of these regulations, the term - -

(a) "**Bureau of BFAD**" shall refer to the Bureau of Food and Drugs.

(b) **"Constructive knowledge"** as herein 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 or purchase from a BFAD licensed 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 the BFAD.

(g) **"PSD"** Shall mean Product Services Division of the BFAD.

(h) **"Unregistered imported drug product"** as distinguished from counterfeit drug defined under Section 3 of R.A. 8203, 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, the 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 5 of R.A. 8203 are likewise made liable under these rules.

RULE III

MONITORING OF COUNTERFEIT DRUGS

Section 1. **Procedure For Monitoring Counterfeit Drugs in The Market.**

(a) The Food And Drug 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' genuineness 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 genuineness 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 genuineness 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

RULE IV

ADMINISTRATIVE PROCEEDINGS

Section 1. **When Initiated by BFAD FDRO's.** 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 be 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 case the party-respondent manifest his intention to present evidence in support of his positon 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 the 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 RA 8203, a memorandum 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 the 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 (30) 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 the receipt of parties or from notice.

RULE V

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 except on the following grounds - - -

(a) Abuse of discretion;

(b) Decision is not supported by substantial evidence; or

(c) Irregularity in the conduct of investigation.

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 genuineness 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 genuineness 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 propio* 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 drug establishment of the said result through the fastest 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 (16) hours from receipt of the notice unseal the suspected drugs for distribution to legitimate commerce.

Section 7. **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 8. **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 products involving their own trademark, trade name or other indentifying 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 sales invoices or official receipts 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 III

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 LICD 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 RA 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 the - -

(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

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 except 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 5. **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 6. **Execution Pending Appeal.** The appeal when filed by the 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 VI

ADMINISTRATIVE SANCTIONS

Section 1. **Minimum Penalty.** An administrative fine of not less than one hundred thousand pesos (PHP 100,000.00) but not more than 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 one hundred thousand pesos (PHP 100,000.00) but not more than three hundred thousand pesos (PHP 300,000.00) 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 three hundred thousand (PHP 300,000.00) but not more than five hundred thousand pesos (PHP 500,000.00) and the permanent closure of the 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 products 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 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 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 of the case will manifest the criminal intent of 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 one hundred thousand pesos (PHP 100,000.00) or the number of drug product subject of the case is 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 are not life saving drug products and the volume of the counterfeit drugs is worth more than one hundred thousand pesos (PHP 100,000.00) but not exceeding one million (PHP 1,000,000.00) pesos 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 regardless of the volume; or the volume of the counterfeit drug products is worth more than one million (PHP 1,000.000.00) pesos.

RULE VII

FINAL PROVISIONS

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

Section 2. **Prospectivity** - The administrative sanctions herein imposed shall not apply to acts committed prior to October 26, 1996 or the effectivity 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.

QUINTIN L. KINTANAR, M.D., Ph.D.,CESO I
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give rise to the presumption of violation as provided under Section 4 (a) of R.A. 8203.

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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 RA 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 in 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 Rule IV hereof.

drug products subject of the case will manifest the criminal intent of the party liable to introduce the commerce counterfeit drug products. This however, shall not preclude any interested party from initiating a criminal action against the party liable independent of BFAD.

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In Consultation with the Department of Health:

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

Date of Issuance: November 19, 1996

(MS.Dec. 4, 1996)