[BFAD, November 19, 1996]

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

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 or 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 products 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 and 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 product's 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 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 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 products 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 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 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 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.

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 RA 8203 has been committed, he/she shall instead file an affidavit of complaint station —

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.

RULE V

Administrative Proceedings