

COMPLAINT VS. PARALLEL IMPORTATION OF PRESCRIPTION DRUGS

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Attached is the letter dated February 8, 2001 of Mr. Leo P. Wassmer, Jr., Executive Vice-President and CEO, Pharmaceutical & Healthcare Association of the Philippines reporting to this Bureau the list of imported medicines which were brought in the Philippines by private importers which were not registered with the Bureau of Food and Drugs and therefore violative of Sections 21-A and B of RA 3720.

The Executive Vice-President and CEO, PHAP is requesting that other similarly classified incoming shipments be held until the importer presented License to Operate issued by BFAD and a Certificate of Product Registration for each products.

For your information and guidance.

Adopted: 01 Mar. 2001

(SGD.) JULITA S. MANAHAN

Deputy Commissioner, Internal Administration Group

Attachment:

February 8, 2001

Hon. Titus Villanueva
Commissioner
Bureau of Customs

Dear Hon Villanueva:

We recently received a price list of parallel imports, a copy of which we are forwarding you. The products in this list were reportedly brought in by a private importer and are being peddled to dispensing physicians and small drug stores.

We are definite that the products in this list are not registered with the Bureau of Food and Drugs (BFAD) because the Chief of the BFAD Products Services Division has stated that no Certificate of Product Registration has been issued to any private parallel importer. Moreover, there are still no guidelines on this registration of these products.

The importation of these products violate certain provisions of RA 3720, as amended, which we quote as follows:

"Section 21-A. No person shall manufacture, sell, offer for sale, import, export, distribute or transfer any drug or device without first securing a license to operate from the Bureau after due compliance with technical requirements in accordance with the rules and regulations promulgated by the Secretary pursuant to this Act.

"Section 21-B. No drug or device shall be manufactured, sold, offered for sale, imported, ex-ported, distributed or transferred, unless registered by the manufacturer, importer of distributor thereof in accordance

with the rules and regulations promulgated by the Secretary pursuant to this Act..."

Also. RA 8203, the Special Law on Counterfeit Drugs, classifies as counterfeit,

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

Taking these legal provisions unto account, the products in attached list should not have been released by Customs. However, since they may no longer be under your bureau's jurisdiction, we strongly suggest that similarly classified incoming shipments be held until the importer could show a License to Operate issued by the BFAD and a Certificate of Product Registration for each product.

Sincerely yours.

(SGD.) LEO P. WASSMER. JR
Executive Vice-President & CEO

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