



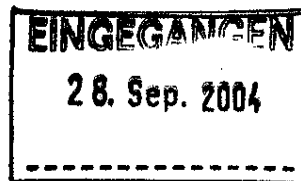
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

9/9/2004

Detlov Goj
Ovamed GmbH
Klebitzorn 33 - 35
22885 Barsbüttel
Germany



Dear Mr. Goj:

This correspondence is in response to your letter dated 9/2/2004, addressed to the U.S. FDA Division of Import Operations, requesting information regarding the entry of U.S. citizens carrying medications manufactured by your firm that are unapproved in the U.S.

Under certain circumstances, FDA allows consumers to import drugs otherwise considered to be illegal in the U.S., as a matter of enforcement discretion. Under this policy, FDA permits individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product.

This policy does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States.

Enclosed is a copy of the "Coverage of Personal Importations" subchapter to FDA's Regulatory Procedures Manual, which provides further detail into our policy. Also enclosed is a copy of "Traveler Alert: Importation of Prescription Medicines/Drugs". You may provide these documents to your patients, or direct them to FDA's website <http://www.fda.gov/importeddrugs/> which contains the enclosed information plus additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "John E. Verbeten".

John E. Verbeten, CSO
U.S. Food and Drug Administration
Division of Import Operations and Policy

enclosures

Importation of Prescription Medicines/Drugs

Traveler Alert

The U.S. Customs Service enforces Federal laws and regulations, including those of the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA).

The United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 331(d), and 355(a)), which is administered by FDA, prohibits the interstate shipment (which includes importation) of **unapproved** new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness. It is the importer's obligation to demonstrate to FDA that any drugs offered for importation have been approved by FDA.

FDA has developed guidance entitled "**Coverage of Personal Importations**" which sets forth that agency's enforcement priorities with respect to the personal importation of unapproved new drugs by individuals for their personal use. The guidance identifies circumstances in which FDA may consider exercising enforcement discretion and refrain from taking legal action against illegally imported drugs. Those circumstances are as follows:

- "1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
 - 2) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue;
 - 3) the product is considered not to represent an unreasonable risk;
- and
- 4) the individual seeking to import the product **affirms in writing** that it is for the patient's own use (generally not more than a 3 month supply) and **provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment** with the product, or **provides evidence that the**

product is for the continuation of a treatment begun in a foreign country." (Emphasis added)

FDA's guidance is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S. Even if all of the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized. The guidance represents FDA's current thinking regarding the issues of personal importation and is intended only to provide operating guidance for FDA personnel. The guidance does not create any legally enforceable rights for the public; nor does it operate to bind FDA or the public.

To avoid travel delays and to prevent possible harm from taking unsafe or ineffective medications, residents and visitors upon arrival to or departure from the U.S. should keep in mind the following precautions:

- Do not assume that medications which are legal in foreign countries are also approved for use in the United States. These products may be illegal and may include addictive and dangerous substances;
- Be aware that the labeled uses (conditions for which the product is represented to be effective) for a product purchased outside the U.S. may not be approved in the United States;
- It can be dangerous to take some medications without medical supervision. The reason why some medications are limited to prescription use in the United States is that either they are unsafe without medical supervision or a medical diagnosis is required to ensure that the medication is appropriate for your condition;
- Avoid purchasing any drug products that are not approved for sale in the U.S. (including foreign-manufactured versions of U.S. approved drugs). FDA cannot assure that these products conform to the manufacturing and quality assurance procedures mandated by U.S. laws and regulations and, therefore, these products may be unsafe. In addition, such products are illegal in the U.S. and, therefore, may be subject to entry refusal;
- Some medications which may appear to be U.S. approved drug products may in fact be counterfeit versions of such products. (The term "counterfeit drug" is defined as "a drug which, or the container or labeling of which, without

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authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor." See 21 U.S.C. 321(g) (2));

- In the event you develop complications from using a medication which require medical attention, your treatment could be delayed or made more difficult unless there is sufficient information available about the product, such as the generic name of the product, dosage form and strength, and how often you need to take the product.
- Possession of certain medications without a prescription from a physician licensed in the United States may violate Federal, State, and/or local laws;
- It is important to have medications in the originally-dispensed container;
- FDA's personal importation guidance provides that when bringing unapproved drugs into the U.S. for use in treating serious or life threatening illnesses, such products should be used under the care and supervision of a U.S. licensed physician. It is advisable to make available for examination by U.S. Customs Inspectors or other appropriate government authorities appropriate documentation of such monitoring;
- It is against the law not to properly declare imported medications to U.S. Customs.
- When the type of drug, the quantity, or the combination of various drugs arouse suspicions, U.S. Customs Inspectors will ordinarily contact the nearest FDA or DEA office for advice and will then make a final determination about whether to release or detain the article. (See 19 U.S.C. 1499).

In addition to federal requirements, individual States may have additional requirements covering prescription (Rx) or controlled medications. Travelers should check with State authorities, where they reside or are traveling, to verify that a particular prescription does in fact comply with State regulations. In many areas, the local police department and pharmacies can provide additional information.

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For more detailed information on FDA's personal importation guidance, contact your local FDA office, or check out FDA's Internet website at:

http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html

SUBCHAPTER COVERAGE OF PERSONAL IMPORTATIONS

PURPOSE

To provide guidance for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. This guidance clarifies how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the U.S. Customs Service. It is expected that a Customs officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown r to health.

When items in personal baggage are brought to FDA's attention, the district office should use its discretion, on a case-by-case basis, in accordance with the guidance provided under GENERAL GUIDANCE below, in deciding whether to request a sample, detain the article, or take other appropriate action.

MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by Customs in accordance with the guidance provided under GENERAL GUIDANCE below, using the following procedures:

Prepare a Collection Report for each parcel sampled. Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes. If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory. The remaining portion should not be removed from the custody of the Customs Mail Division.

Importations detained in accordance with this guidance should be held by Customs until they are either released or refused entry. Attached as guidance are two specimen letters that may be sent with the Notice of Detention and Hearing when a parcel is detained. (See **Exhibit 9-3** for use in general mail importations and **Exhibit 9-4** for use in unapproved drug or device mail importations).

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the Customs Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of Customs.

GENERAL GUIDANCE

The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or automatic detention based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by Customs, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to Customs for handling.

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
2. when a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of

a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient's physician should consider for example, enrolling the patient in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to the Division of Import Operations and Policy (HFC-170) the issuance of an import alert if they encounter:

1. personal importation of products that represent either a direct or indirect health risk; or
2. the promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*(See Compliance Policy Guides Manual, Section 120.500, "Health Fraud - Factors in Considering Regulatory Action" (CPG 7150.10))