FDA Regulations
The following criteria must be met to Import Medications into the United States

It is legal for US residents to import medications from outside the US provided the following conditions are met:

A) The product was purchased for personal use and does not exceed a 3 month supply.
B) The product is not for resale.
C) The intended use of the product is appropriately identified.
D) The patient seeking to import the product affirms in writing that it's for the patient's own use.
E) The patient provides the name and address of the doctor licensed in the US responsible for his or her treatment.
F) The medication is not a controlled substance, e.g. sleeping pills, Valium, narcotics.

Note: Probably 99% of all medication shipments entering the US don't meet the above conditions but the packages are allowed to enter the country anyway. US Customs does occasionally spot check a very small percentage of packages. If one orders medications from offshore often enough, the chances are that eventually US Customs will open and inspect one of your packages. If the package doesn't contain narcotics or controlled substances, they normally reseal the package and release it for delivery by mail. In the very unlikely event that a package is detained, US Customs normally sends a letter informing the recipient that they need to mail a copy of a doctor's prescription or else the package will be returned to sender or destroyed. To repeat, it is not illegal to order medications from abroad for personal use. The official FDA policy on medication importation follows below.

FDA POLICY ON MEDICATION IMPORTATION

July 20, 1988
FROM: Director, Office of Regional Operations
SUBJECT: Pilot Guidance for Release of Mail Importations
TO: Regional Food & Drug Directors, District Directors, Import Program Managers, Compliance Branch Managers, Investigations Branch Managers, Laboratory Branch Directors
INFO: All Major Field Offices, Resident Posts, Division of Field Science, Division of Federal-State Relations, Office of Legislative Affairs.
NOTE: This guidance is being issued on a pilot basis and is subject to change and/or cancellation. If the pilot proves successful, with no significant problems, Chapter 9-71 of
Because of the desire to acquire articles for treatment of serious and life-threatening conditions like AIDS and cancer, individuals have been purchasing unapproved products from foreign sources. Some of these products are sold over-the-counter in the country of origin, while others are available from clinics where the purchaser was treated. Such products are often shipped to the purchaser by mail.

Even though such products are subject to refusal, we may use our discretion to examine the background, risk, and purpose of these products before making a final decision. To assure that the districts are operating in a uniform manner, the following guidance is provided for dealing with personal use shipments.

1. Except as modified by these instructions, established guidance found in RPM-9-71, exhibits X9-71-1 and X9-71-2 should be followed.

2. A product entered for personal use, which meets the criteria in item 4 below, may proceed without sampling or detention.

3. Products that are not identified, or are not accompanied by documentation of misrepresentation, or an unreasonable health risk due to either toxicity or possible contamination.

In such cases, the appropriate center should be contacted for guidance concerning release of the product.

4. Following detention, shipments may be released to an individual if the following criteria can be satisfied and there is no safety risk or evidence of fraud:

   a. The product was purchased for personal use.

   b. The product is not for commercial distribution and the amount of the drug is not excessive (i.e., a three-month supply or less).

   c. The intended use of the product is appropriately identified.

   d. The patient seeking to import the product affirms in writing that it is for the patient's own use and provides the name and address of the doctor licensed in the US responsible for his or her treatment with the product.

5. If the district should encounter a situation suggesting promotional and/or commercial activity that falls within our health fraud guideline, the district should recommend that an import alert be issued for the automatic detention of the product and identification of the promoter involved.

6. The model letter currently in exhibit X9-71-2 should be revised according to the attached during this pilot.

7. The article may then be released with comment upon receipt of the letter as follows: