Personal Importation Policy (PIP) Frequently Asked Questions (FAQs)

Q. What is the Personal Importation Policy?

A. The Personal Importation Policy, also known as the PIP, is a guidance that sets forth FDA's enforcement priorities related to the personal importation of drugs that are not FDA-approved and, therefore, are in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) and subject to enforcement action. FDA recognizes there are circumstances under which a United States citizen may wish to seek treatment with an unapproved drug that is not domestically available, or a foreign citizen traveling to the United States may wish to continue treatment with a foreign drug that is not domestically available. The PIP was developed to address such circumstances and gives FDA instructions on exercising its enforcement discretion to permit importation of drugs otherwise considered illegal in the United States. In determining whether exercise discretion is warranted, FDA considers the following factors:

- The drug must be unapproved and intended for use in a serious medical condition for which there is no effective treatment domestically available
- There must be no commercialization or promotion of the drug in the United States
- The drug cannot represent an unreasonable health risk to the patient
- The request must be accompanied by an affirmation that the drug is for the patient's use only and by the name and address of the United States–licensed physician responsible for the patient's treatment
- The request is generally for no more than a 3-month supply of the drug

The PIP does not give a license to individuals to import unapproved drugs for personal use into the United States. It does not change the law or create or confer any legally enforceable rights, privileges, or benefits on or for any individual, and it does not bind the FDA or the public.

Q. Can I use the PIP to get less expensive drugs from Canada?

A. No, the PIP is not intended to permit personal importation of cheaper versions of FDA-approved drugs from Canada or other foreign countries. FDA cannot assure that foreign-made versions of FDA-approved drugs have been properly manufactured, are safe and effective, and are exactly the same formulation as the FDA-approved versions. The PIP is intended to make available, through the exercise of enforcement discretion, unapproved drugs used to treat serious medical conditions for which no equivalent treatment exists in the United States, and unapproved drugs used to continue treatment begun in a foreign country.

Q. What kinds of drugs are eligible for importation under the PIP?

A. The PIP is intended to apply to unapproved drugs that are:

- used to treat serious medical conditions
- not a serious health risk to patients
- not commercially available or marketed in the United States
- part of a treatment regimen begun in a foreign country

Unapproved drugs that appear on Import Alert, that is, drugs that appear to be in violation of the FDCA and are subject to detention without physical examination, are not eligible for

importation under the PIP. Likewise, drugs with associated Risk Evaluation and Mitigation Strategies (REMS) requiring distribution of FDA-approved patient medication information necessary for safe and effective use of the drugs also are not eligible for importation under the PIP.

Q. Do I need a prescription to get drugs using the PIP?

A. No, the guidance does not specify that a prescription for the unapproved drug is required for consideration of importation using the PIP. However, to help facilitate a timely decision, the unapproved drug offered for importation under the PIP should be accompanied by a letter explaining the intended use of the drug, including the name and address of the United States–licensed physician responsible for the patient's treatment with the drug, and affirming the drug will be used only for the individual patient and not distributed to others.

Q. How much drug can I get at one time using the PIP?

A. The PIP generally permits up to a 3-month supply of the unapproved drug.

Q. What forms do I use to request drugs using the PIP?

A. There is no formal mechanism or form used to authorize importation of unapproved drugs under the PIP. The PIP is merely an operating guidance for FDA personnel to use enforcement discretion under certain circumstances. Therefore, each request is evaluated on a case-by-case basis.

PIP Links

http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm

http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm

http://www.fda.gov/NewsEvents/Testimony/ucm115214.htm