

Alternative Funding Programs & International Importation

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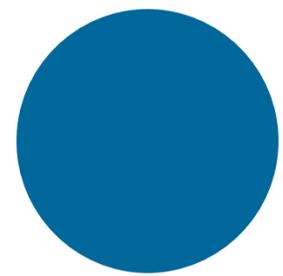


About the Cystic Fibrosis Foundation

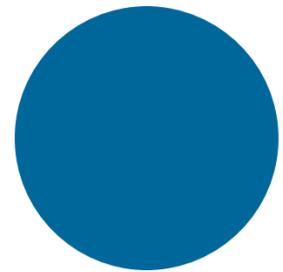
- Non-profit organization dedicated to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care
- Cystic fibrosis is a rare genetic disease close to 40,000 children and adults and can affect every racial and ethnic group in the United States
- Through development of transformative therapies and careful, aggressive, and continuously improving disease management, the life expectancy of someone born with CF has doubled in the last 30 years



Laws and Regulations Related to Drug Importation



FDA's Personal Importation Policy



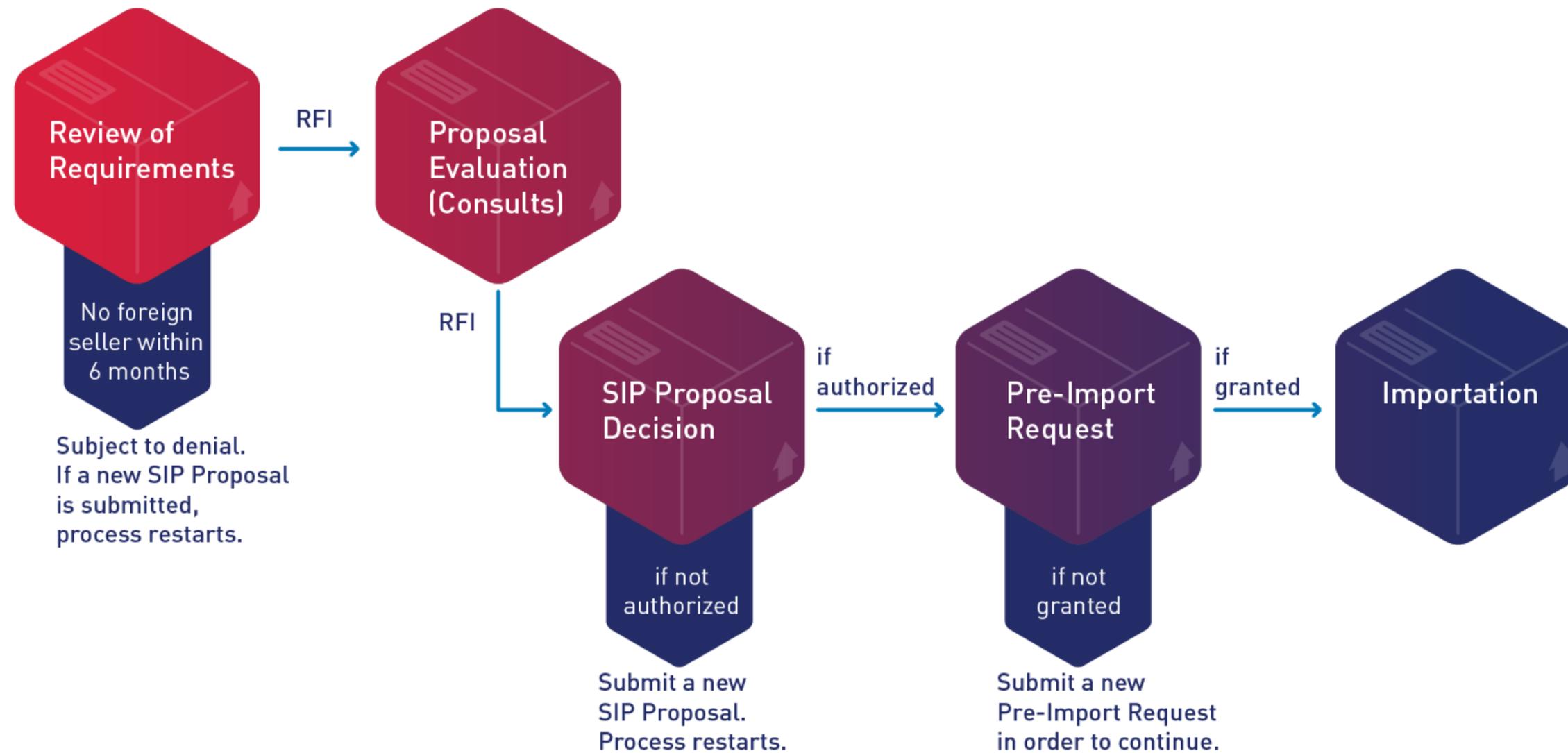
Section 804 Importation of Prescription Drugs from Canada

FDA's Personal Importation Policy

The personal use policy provides that an individual may be permitted to import an unapproved prescription drug for personal use if:

1. The product is not used to treat a serious condition, such as the use of an over-the-counter treatment (OTC); or
2. The product is used to treat a serious condition; and
 - a. The product is needed to treat the serious condition and the medication is not available in the United States;
 - b. There is no commercialization or promotion of the drug to U.S. residents;
 - c. The drug does not represent an unreasonable risk;
 - d. The quantity is not more than a 3-month supply; and either:
 - i. The consumer provides contact information for the U.S. doctor providing treatment with the drug; or
 - ii. The consumer provides evidence that the product is for continuation of treatment begun in a foreign country

Section 804 of FDCA



Patient Risk

Lack of Proper Storage and Handling

The FDA and state pharmacy laws mandate strict temperature and handling regulations to maintain medication efficacy.

Insufficient Transparency

Foreign medications frequently lack essential labeling, patient instructions, and recall mechanisms, leaving patients vulnerable to severe health risks

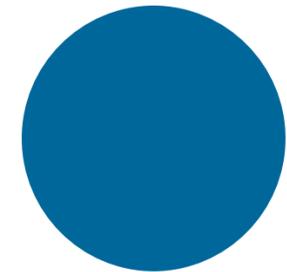
Risk of Counterfeit Medications

Purchase of medications directly from foreign pharmacies side-steps the Drug Supply Chain Security Act tracking system and operate outside the closed U.S. supply chain.

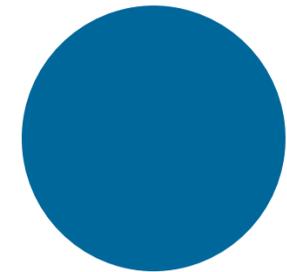




What can State Policymakers Do?



Ensure scrutiny and oversight is incorporated in SIP application and implementation particularly for drugs approved to be imported



Work with FDA to enforce existing laws against illegal importation

