

# U.S. Agent and Importer Requirements

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Electronic Registration and Listing Using CDER Direct

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# Learning Objectives

- Describe U.S. agent requirements
- Describe U.S. agent responsibilities
- Describe importer requirements

# U.S. Agents

- An authorized person/ business which represents a foreign drug manufacturing establishment **in the United States.**



# Importer

- A person **in the United States** that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's drug, that is imported into the U.S.



# U.S. Agent and Importer data

- Included on a foreign establishment's registration SPL
- Only one U.S. agent
- Can include many importers

# U. S. Agents Requirements



- Must reside or maintain a place of business in the U.S.
- The address may not be a mailbox
- The address **may not** be a place where a person acting as the U.S. agent is not physically present



# U.S. Agent Responsibilities

- Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications
- Responding to questions concerning those drugs that are imported or offered for import to the U.S.
- Assisting FDA in scheduling inspections

# Generally

*FDA's providing information and/or documents to the United States agent is equivalent to providing the same information and/or documents to the foreign registrant.*



# Importer Responsibilities

- Consigning and shipping a drug from a foreign country to the U.S.
- Data required at the time of importation
- Each imported drug can have a different importer, and all importers must be included on the foreign establishment's registration SPL

# Important Considerations

- A vendor can act as a U.S. agent, as long as it assumes all the required responsibilities of a U.S. agent
- If a U.S. agent or importer is included on an establishment registration without their knowledge/ authorization:
  - Contact the firm
  - FDA may take action

# Challenge Question

Who is responsible for ensuring the accuracy of registration and listing information?

- U.S. agent
- Importer
- Official contact
- Company CEO

# Questions?

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