

Establishment Registration Highlights

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Electronic Drug Registration and Listing (eDRLS) Using CDER Direct -
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Learning Objectives



- Identify establishment business operations
- Provide requirements for the U.S. Agents
- Describe the role of importers
- Understand mergers and acquisitions

What are establishment business operations



- Business operations describe manufacturing activities performed
- Facilities performing multiple operations should list **all** operations in the SPL
- Used to access statutory fees, inspection planning, and drug volume reporting

Business Operations



SPL Acceptable Term

ANALYSIS

API/FDF ANALYTICAL TESTING

API MANUFACTURE

CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY

DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE LABEL

FDF MANUFACTURE

HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY

IMPORT

IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING

LABEL

MANUFACTURE

MEDICATED ANIMAL FEED

MANUFACTURE <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation>

OUTSOURCING ANIMAL DRUG COMPOUNDING

PACK

PARTICLE SIZE REDUCTION

POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION

RELABEL

REPACK

SALVAGE

SIP FOREIGN SELLER

STERILIZE

THIRD-PARTY LOGISTICS PROVIDER

TRANSFILL

UNITED STATES AGENT

WHOLESALE DRUG DISTRIBUTOR

Code

C25391

C101509

C82401

C101511

C73608

C101510

C112113

C73599

C101512

C84732

C43360

C84635

C122061

C84731

C84386

C91403

C73607

C73606

C70827

C175317

C84382

C118412

C125710

C73330

C118411

Business Operations



- Business operations on the SPL page include business operations for all submissions (503B submissions, DSCSA submissions, etc.)
- An SIP Foreign Seller can only be located in Canada

Requirements for U.S. Agent



Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug imported into the United States must identify a United States Agent (U.S. agent) for that establishment.

Outlined in 21 CFR 207.69(b)

Requirements for U.S. Agent

- The United States Agent is responsible for:
 - Responding to FDA questions concerning drugs offered for import
 - Reviewing, disseminating, routing, and responding to all communications from FDA
- FDA is providing data to U.S. Agent equivalent to providing data to foreign establishment

Unauthorized U.S. Agent



- Unauthorized inclusion of a U.S. Agent in a foreign establishment registration:
 - May cause FDA's inactivation of the registration record
 - U.S. Agent may check (DECERS) periodically to find unauthorized use.

Drug Importers

- Imported drugs must meet FDA's standards for quality, safety, and effectiveness
- FDA will verify compliance with the following requirements, as applicable:

Registration and listing

Drug application

Drug labeling

Drug current good manufacturing practices (cGMPs)

Drug Importers



- Required for foreign establishments subject to registration (21 CFR 207.1)
- Importer means, for purposes of this part, a person in the United States that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's drug, or an animal feed bearing or containing a new animal drug, that is imported into the United States

Drug Importers

- FDA verifies that the declared manufacturer is registered, and the product is listed
- FDA verifies the foreign manufacturer has identified the declared importer or consignee in their registration
- If the information does not match, the FDA may need to gather additional information, detain the product, or refuse entry

Mergers and Acquisitions



- Companies can merge, establishments can be acquired
- In terms of registration:
 - Any establishment moving from one registrant to another, should be removed from the initial SPL and moved to acquiring company's registration SPL
 - DUNS and FEI may remain the same or change

Challenge Question #1



The business operation must reflect the functions the facility performs for:

- A) Inspection planning
- B) Assess statutory fees
- C) Drug volume reporting
- D) All of the above

Challenge Question #2



If my establishment only repacks and relabels one product, do I need to list both operations?

- A) No, only use the business operation that sells the most product
- B) List the business operation with the lowest fee
- C) List all business operations the facility performs
- D) Email eDRLS and explain what you manufacture

Challenge Question #3

- Where can I read the requirements to become a U.S. Agent?
- A) 21 CFR 207.69(b)
- B) 21 CFR 207.96(b)
- C) 21 CFR 209.67(c)
- D) CFRs are only suggestions

Summary



- Use correct business operations to identify establishments
- Foreign establishments require U.S. Agents
- Verify compliance with FDA before importing drugs into U.S. market

Resources



- <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>
- <https://www.fda.gov/industry/structured-product-labeling-resources/business-operation-qualifier>
- <https://www.fda.gov/industry/importing-fda-regulated-products/importing-human-drugs#timeofimport>
- [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207#:~:text=https%3A/%E2%80%8B/%E2%80%8Bwww.ecfr.gov/%E2%80%8Bcurrent/%E2%80%8Btitle%2D21/%E2%80%8Bpart%2D207%23p%2D207.1\(Importer\)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207#:~:text=https%3A/%E2%80%8B/%E2%80%8Bwww.ecfr.gov/%E2%80%8Bcurrent/%E2%80%8Btitle%2D21/%E2%80%8Bpart%2D207%23p%2D207.1(Importer))

Questions?

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