Establishment Registration Highlights

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Electronic Drug Registration and Listing (eDRLS) Using CDER Direct - 2024
SBIA Workshop – September 12, 2024

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	Code
ANALYSIS	C25391
API/FDF ANALYTICAL TESTING	C101509
API MANUFACTURE	C82401
CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY	C101511
DISTRIBUTES DRUG PRODUCTS UNDER OWN PRIVATE LABEL	C73608
FDF MANUFACTURE	C101510
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	C112113
IMPORT	C73599
IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING	C101512
LABEL	C84732
MANUFACTURE	C43360
MEDICATED ANIMAL FEED	C84635
MANUFACTUREhttps://www.fda.gov/industry/structured-product-labeling-resources/business-operation	
OUTSOURCING ANIMAL DRUG COMPOUNDING	C122061
PACK	C84731
PARTICLE SIZE REDUCTION	C84386
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION	C91403
RELABEL	C73607
REPACK	C73606
SALVAGE	C70827
SIP FOREIGN SELLER	C175317
STERILIZE	C84382
THIRD-PARTY LOGISTICS PROVIDER	C118412
TRANSFILL	C125710
UNITED STATES AGENT	C73330
WHOLESALE DRUG DISTRIBUTOR	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 (DECRS) 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)

Questions?

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