Complying with Drug Listing Requirements

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Electronic Drug Registration and Listing (eDRLS) Using CDER Direct

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Learning Objectives

- Describe drug listing requirements under 21 CFR 207
- Identify common listing issues
- Explain the compliance program and listing deficiency letter highlights
- Describe effects of non-compliance

Drug Listing Requirements

- Section 510 FD&C Act 21 U.S.C. 360(j)(1)
- Subpart D of 21 CFR 207
  - 207.41- who must list and what drugs must be listed
  - Each registrant must list each drug it manufactures, repacks, relabels, or salvages for commercial distribution
  - Requirements under 207.49, 207.53, and 207.54 must be followed for listing information
    - Private Label Distributors (PLDs) and Contract Manufacturer Organizations (CMOs)

Drug Listing Requirements

- 207.45 - When must the initial listing be submitted
  - No later than 3 calendar days after initial registration of establishment

Drug Listing Requirements

- 207.49 - Manufacturer requirements
- 207.53 - Repackager and relabeler requirements
  - Correct use of NDCs in appropriate sections of listing submission
- 207.54 - Drug salvager requirements

Drug Listing Requirements

- 207.57- Requirements for updating listing information
  - Every June and December
  - FDA requests updates to be submitted as soon as possible
  - Blanket “No Changes” Certification SPL
    - October to December each year

Where is Listing Data Found

- The National Drug Code(NDC) Directory
  - Listing data submitted to FDA by labelers
    - Active and finished and unfinished drug products
  - Listing data removed from NDC Directory if
    - End marketing data has reached
    - Compliance case is not resolved
    - Not updated or certified
  - Updated daily

Common Listing Issues

- Incorrect/ missing DEA Schedule
- Incorrect NDC
- Incorrect marketing category or document type
- Incorrect marketing authorization
  - Application number
  - Monograph ID
- Labeling issues: incomplete or outdated labeling
- Incorrect strength or strength conversion

Compliance Program

- Started in 2015
- Mission: to protect and promote public health by striving to achieve accuracy and integrity of establishment registration and drug listing data
- Phases of compliance actions:
  - Review of data
  - Deficiency letter
  - Data removal
  - Further actions – untitled letter, warning letter, data inactivation

Compliance Program

Drug listing deficiency Letter Highlights

- Statement of deficiency in 1st paragraph and in summary table
- 30 days for corrections
- **Non-delivery of letter does not stop the process**
- Further actions that may be taken - data removal, UL, WL and data inactivation
- Instructions for submitting corrections

Complying with Listing Requirements

- Read and follow the requirements under 21 CFR 207
- Read the deficiency letter and follow the instructions
- Revise listing file with corrections
- If you encounter errors:
  - Send Core-ID or Submission-ID to edrls@fda.hhs.gov for review and approval of manual override
  - Send approval to SPL coordinator spl@fda.hhs.gov to request a manual override

Importance of Drug Listing

- Post market surveillance
- Recalls
- Monitoring of shortages
- Adverse event reporting
- Supply chain security
- Identification of unapproved products in the market
- Drug import and export

Effects of Non-Compliance

- Public safety concerns and medication errors
- Data removal - from NDC Directory
- Publication of WL
- Data inactivation
  - CMS reimbursement issues
  - Importation issues

Challenge Question 1

True or False:

Incomplete or outdated *labeling* is a type of *listing* issue

Challenge Question 2

Select the true statement(s) about the NDC Directory

A. FDA publishes the drug listing information in the NDC Directory

B. The NDC Directory is updated once a week

C. The NDC Directory contains inactivated data

D. All these statements are true

Challenge Question 3

How can you ensure compliance with listing requirements?

A. Follow 21 CFR 207

B. Read and follow the deficiency letter and respond within 30 days

C. First send DRLB the Submission-ID or Core-ID of the failed submission for review and approval

D. All the above

Summary

- Follow 21 CFR 207
- Follow instructions in the deficiency letter
- Update outdated information
- Remember non-compliance will result in negative outcomes

Closing Thought

Avoid issues

Submit the drug listing correctly the first time

Resources

- 21 CFR 207:
  - https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207
- NDC Directory:
  - https://dps.fda.gov/ndc
- DRLB Compliance Program https:
  - //www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-registration-and-listing-compliance-program

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Questions?

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