

Complying with Drug Listing Requirements

Tasneem Hussain Pharm. D

Pharmacist, Consumer Safety Officer

Division of Labeling, Registration, and Unapproved Drugs

Office of Unapproved Drugs & Labeling Compliance

OC | CDER | US FDA

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- Labeling issues: incomplete or outdated labeling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>



Questions?

eDRLS@fda.hhs.gov



