CDER Direct Drug Listing

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Overview

- Who must list
- When to list
- How to submit a Drug Listing SPL using CDER Direct
- Summary
- Do’s & Dont’s
- Helpful Resources
- Challenge Questions

In Brief

- Goal, to help registrants submit accurate, compliant

Product listings

- Accurate listings facilitate efficient engagement with FDA

“Who”

- Each registrant must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution (21 CFR §207.41).
- Contract manufactures (CMO) must list under their own labeler code.
- CMO who manufacture for private label distributors (PLD) must also list for PLDs, using the PLD’s labeler code. PLDs may list their own products as an authorized agent.

“When”

- Initial- Listing information must be submitted within 3 days of the initial registration (21 CFR §207.45)
- Updates- You can update any changes to the listing every June and December, preferably ASAP (21 CFR §207.57)
- Annual listing certification- Accepted updates to the listing certifies your listing for the calendar year and the next calendar year (21 CFR §207.57)

CDER Direct
Electronic Submissions Portal

LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I Understand

LOGIN Forgot your password?

QUICK LINKS

- Register With CDER Direct
- Resources
- Tutorials
- Help Desk
- FAQs

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. Click here to create a new account.

If you already have an account, enter your **Username** and **Password**.

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

Browser Compatibility: The CDER Direct portal currently works best with the following browsers:

- Microsoft Edge
- Firefox version 28 and above
- Google Chrome
- Safari 10.0.1 and above

NOTIFICATIONS

Summary

- Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S and their representative labeling
- Listing data is also used by the public including healthcare providers and other organizations in academia and industry
- Have a standard operation procedure or system in place to verify the accuracy of listing at least twice a year

Drug Listing

Do's

- Registrants must list all drugs they manufacture
- Check listings at a minimum every June and December for accuracy
- Private Label Distributors (PLDs) may list own drug
- Include the complete supply chain under "Establishments"
- Include Inactive ingredients (can be marked confidential)

Dont's

- Don't list non-drugs with CDER
- Don't make assumptions
- Don't omit data to pass automated validations
- Don't include multiple email addresses when requesting for assistance

Helpful resources

- Electronic Drug Registration and Listing instructions
- Strength Conversion in Drug Listing
- OTC Active Ingredients
- Electronic Code of Federal Regulations
- edrls@fda.hhs.gov

Challenge Question #1

True or False: A product listing can be listed without labeler code

- True
- False

Challenge Question #2

True or False: You are not required to provide establishment information in product listing

- True
- False