CDER Direct Drug Listing

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

- Create a listing SPL
- Enumerate data elements required for drug listing
- Explain the timing for initial drug listing to FDA

“Who”

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

“What”

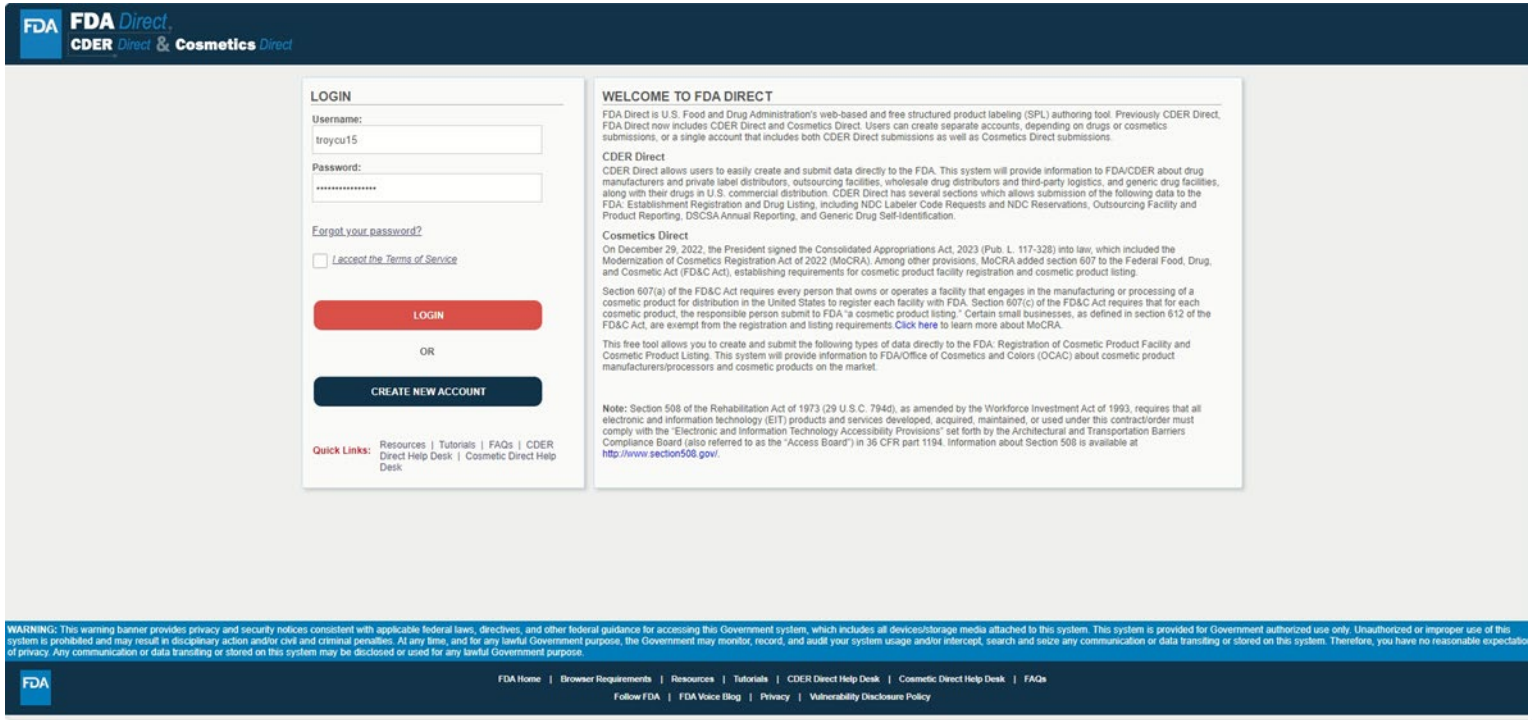
Drug listing requirements are different for:

- Manufacturers (21CFR 207.49)
- Repackagers and relabelers (21CFR 207.53)
    - Notably, the Source NDC
- Drug Salvagers (21CFR 207.54)
    - Notably, the lot number and expiration date

“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- Certifies there were no changes to a previously listed drug (21 CFR 207.57)

Live Demonstration



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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
- Keep a standard operation procedure or system in place to verify the accuracy of listing at least twice a year

Drug Listing

Do's

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

Don’ts

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

In Brief

- Goal of this presentation is to help registrants submit accurate, compliant product listings
- Accurate listings facilitate compliance and efficient engagement with FDA

Helpful Resources

- Electronic Drug Registration and Listing instructions
  (https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions)
- Strength Conversion in Drug Listing
  (https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system- edrls/strength-conversion-drug-listing)
- OTC Active Ingredients
  (https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/over-counter-otc-related-federal-register-notices-ingredient-references-and-other-regulatory)
- Electronic Code of Federal Regulations
  (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207?toc=1)
- edrls@fda.hhs.gov

Challenge Question #1

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

- True
- False

Challenge Question #2

True or False: You must provide an active establishment information in product listing

- True
- False

Challenge Question #3

True or False: There's no limit to how many products you can submit within the same SPL file.

- True
- False


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