

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 manufacturers (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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WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct
CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DISCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct
On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.
Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic product manufacturers/processors and cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794c), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

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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)
(<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)
(<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-notice-ingredient-references-and-other-regulatory)
(<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/over-counter-otc-related-federal-register-notice-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)
(<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207?toc=1>)
- [edrls@fda.hhs.gov](https://www.fda.gov/oc/edrls)

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

