

CDER Direct Establishment Registration Demo

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OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct – SBIA 2024 Workshop



Learning Objectives



- Determine who registers and when
- Describe the various Document Types associated with Est. Registration
- Create and submit an Establishment Registration, Registration Renewal, and De-registration

Who Must Register?



- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the United States (21 CFR 207.17)
- Certain exemptions are included under 21 CFR 207.13

When to Register?

- Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment. (21 CFR 207.21(a))
- Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States. (21 CFR 207.21(b))

When to Renew and Update?



- Annual registration renewal to be submitted between Oct. 1 and Dec. 31
- Expedited updates to be provided within 30 days of a change
 - Closing or selling an establishment (De-Registration / Out of Business Notification)
 - Changing an establishment's name or physical address
 - Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent.

Establishment Registration Document Types



- Establishment Registration
- No Change Notification
- Establishment De-Registration
- Out of Business Notification

<https://direct.fda.gov>

FDA

FDA

FDA Direct
CDER Direct & Cosmetics Direct

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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, OCSA 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 of 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. 794d), 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/>.

All Submissions

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

Outsourcing Facility Registration
Compounded Drug Reporting

DSCSA ANNUAL REPORTING

Wholesale Drug Distributor and Third-Party Logistics Provider Reports

GENERIC DRUG SELF-IDENTIFICATION

Generic Facility GDUFA Self-Identification

COSMETIC REGISTRATION AND LISTING

Registration of Cosmetic Product Facility
Cosmetic Product Listing

SELF HELP

Structured Product Labeling Resources

ALL SUBMISSIONS

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact CDRLS@fda.hhs.gov.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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SUBMISSION ACCEPTED	835fb90e-d5b9-25c0-e053-2a91ab0abc1e	835fb90e-d5b9-25c0-e053-2a91ab0abc1e	cd9604962731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

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<div><input type="text" value="Q"/> <input type="button" value="GO"/> <input type="button" value="ACTIONS"/></div>								
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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SUBMISSION ACCEPTED	833ff90e-dfb9-25c0-e063-2a91ab0abc1e	833ff90e-dfb9-25c0-e063-2a91ab0abc1e	cd8604962731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

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Challenge Question #1



Who should not register as a drug establishment?

- A. Firm that is solely a Private Label Distributor
- B. Manufacturers
- C. Relabelers
- D. Contract Manufacturers

Challenge Question #2



During what period can I update my Establishment Registration?

- A. January 1 - January 31
- B. October 1 – December 31
- C. June 1 – June 30
- D. Any time of the year

Summary



- Register and update on time – it's easy!
- You can manage multiple establishment locations on one Establishment Registration
- Ensure your DUNS information is up-to-date with D&B
- Firms that are solely Private Label Distributors should not register as a drug establishment

Resources



- <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207>
- <https://dps.fda.gov/decrs>
- <https://direct.fda.gov/>

