

How to Submit an Establishment Registration

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CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT
October 13, 2021

Who Must Register?

- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the U.S.
- Certain exemptions are listed on the [eDRLS website](#).



When to Register?

§207.21 When must initial registration information be provided?

- (a) 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.
- (b) 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.



<https://direct.fda.gov>

LIVE DEMO
on
CDER Direct

This is a **TESTING ONLY** application. [Click here](#) to log into the Production Environment. Any submissions made in the application are not officially submitted to FDA.

COVID-19 Update - As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product. Additional information can be obtained after logging in. (Not applicable to 603B outsourcing or compounding facilities)

LOGIN

Username:

rsamuel2

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

[Create Account](#)

[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 Internet Explorer 8 (IE8) and above
- Firefox version 28 and above
- Google Chrome 44.0.2403.130
- Safari 10.0.1 and above

NOTIFICATIONS

12-SEP-14 **new!** Welcome to CDER Direct.



~~Registration Certificates~~



Establishment Registration Renewal

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When to Update Your Registration



- 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)
 - 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.

Document Types for Establishment Renewal



- Establishment Registration
- No Change Notification



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SUBMISSIONS

(ADD SUBMISSION TYPE)

[NDC/NHRC Labeler Code Request](#)
[Establishment Registration](#)
[Product Listing and Certification](#)
[WDD/3PL](#)

MANAGE ACCOUNT

[Edit User Profile](#)
[Manage Users](#)

COVID-19

(Not applicable to 503B outsourcing or compounding facilities)

To list Hand Sanitizers you first need to submit a Labeler Code Request and an Establishment Registration. When these have been completed you can then submit a Product Listing. Please view the user guides below for each submission type:

[Labeler Code Request](#)
[Establishment Registration](#)
[Product Listing - Hand Sanitizer](#)

ALL SUBMISSIONS

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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
DRAFT	a45cc546-40b0-364c-e053-2a95a9a30e3	9085b0a-da5b-e0e1-e053-2995affa0d4f	-	1	HUMAN OTC DRUG LABEL	John Johnson	15-SEP-2021 21:06:17	
DRAFT	232bd240-3719-54dc-e054-00144fa2c04	232bd240-371e-54dc-e054-00144fa2c04	-	1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	John Johnson	11-AUG-2021 12:23:14	
DRAFT	fb03a06-9eaf-4c35-a110-1635ca7c373	c0825d2-eb31-570e-e053-2995affa0d4f	-	2	HUMAN OTC DRUG LABEL	John Johnson	04-AUG-2021 12:20:15	
DRAFT	54c0b112-c42c-49f1-8a08-d771160953f5	e0025d2-eb25-570e-e053-2995affa0d4f	-	2	HUMAN OTC DRUG LABEL	John Johnson	12-JUL-2021 11:55:17	
DRAFT	2823096e-3d04-70ba-e054-00144fa2759	2823096e-3d05-70ba-e054-00144fa2759	-	1	ESTABLISHMENT REGISTRATION	John Johnson	08-JUL-2021 15:38:19	
DRAFT	c3514375-7090-5b01-e053-2a95affa0d4f	c3514370-7091-5b01-e053-2a95affa0d4f	-	1	HUMAN OTC DRUG LABEL NEW REGISTRATION	John Johnson	28-MAY-2021 09:04:15	
SUBMISSION FAILED	c23d89a0-b00b-4576-e053-2995a99a95af	c2c48171-2ba3-bc1f-e053-2a95affa0d4f	cd1052583674 73982560 41@direct	2	HUMAN PRESCRIPTION DRUG LABEL	John Johnson	20-MAY-2021 10:22:23	
DRAFT	33354aaa-0017-564e-e054-00144fa246c	b3c0009-b0b-3066-e053-2995affa0d4f	-	34	HUMAN PRESCRIPTION DRUG LABEL	John Johnson	13-MAY-2021 11:21:50	
DRAFT	b4d33a62-5048-4d3c-0095-04307a00304	b4b4372-6513-23c1-e053-2a95affa0d4f	-	3	HUMAN OTC DRUG LABEL	John Johnson	13-MAY-2021 11:21:34	
DRAFT	c410b5af-e018-4309-0406-bf7045277b2	b42a977-46a4-40c2-e053-2a95affa0d4f	-	5	HUMAN OTC DRUG LABEL	John Johnson	13-MAY-2021 11:21:16	
DRAFT	5d60363d-bdb0-600b-e053-2995a99a0e5d	7c0000a-0166-1197-e053-2a95affa0d4f	-	4	HUMAN COMPOUNDED DRUG LABEL	John Johnson	27-APR-2021 14:57:52	
DRAFT	a30b29f-2053-1aa-a-e053-2995a99a230	b66c446-fda-057b-e053-2a95affa0d4f	-	2	HUMAN OTC DRUG LABEL	John Johnson	08-APR-2021 14:02:06	
DRAFT	83396ae1-e10c-2a30-e053-2a95affa10a4	b4f666c-8a47-8c82-e053-2995a99a7a50	-	3	HUMAN OTC DRUG LABEL	John Johnson	05-APR-2021 19:06:41	
DRAFT	a5107ba5-103c-a2a5-e053-2995a99a4a1c	b02c709c-3d5b-493d-e053-2995affa0d4f	-	6	HUMAN OTC DRUG LABEL	John Johnson	05-APR-2021 19:06:13	

Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back in to the CDER Direct Electronic Submissions Portal. You will also receive an email from FDA when the processing is complete.

Home Establishment Registration

SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC/NHRC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDD/3PL

ESTABLISHMENT REGISTRATION

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GO

ACTIONS

SEARCH ESTABLISHMENT

CREATE NEW / UPLOAD FILE



Row text contains 'core' ☒ ☒

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
AWAITING ACCEPTANCE	438cd80c-5447-4ac6-e054-0014480a7559	cd7755a7-25fc-4d0d-e053-2a95a7da7600	-	2	TTTTTTTTT	Core	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson	03 OCT 2021 13:44:51	-
SUBMISSION ACCEPTED	438cd80c-5447-4ac6-e054-0014480a7559	438cd80c-5448-4ac6-e054-0014480a7559	cd8267314551060245973@direct	1	TTTTTTTTT	Core	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson	02 OCT 2017 11:00:20	-

1 - 2

**Thank You for
Registering and Re-Registering!**

Contact Us:
eDRLS@fda.hhs.gov

