# How to Submit an Establishment Registration

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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 503B 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.

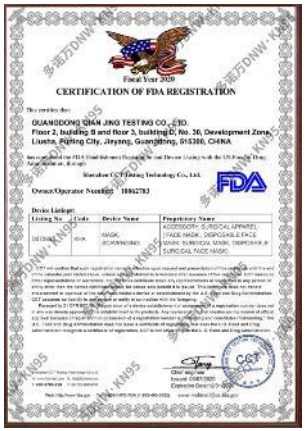
**Is your computer secure?** Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

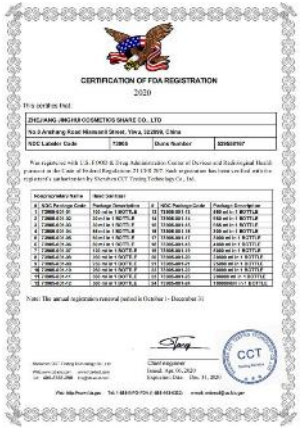
**Browser Compatibility:** The CDER Direct portal currently works best with the following browsers:

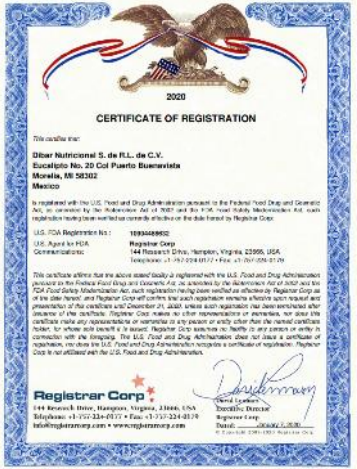
- Microsoft Internet Explorer 8 (IE8) and above
- Firefox version 28 and above
- Google Chrome 44.0.2403.130
- Safari 10.0.1 and above

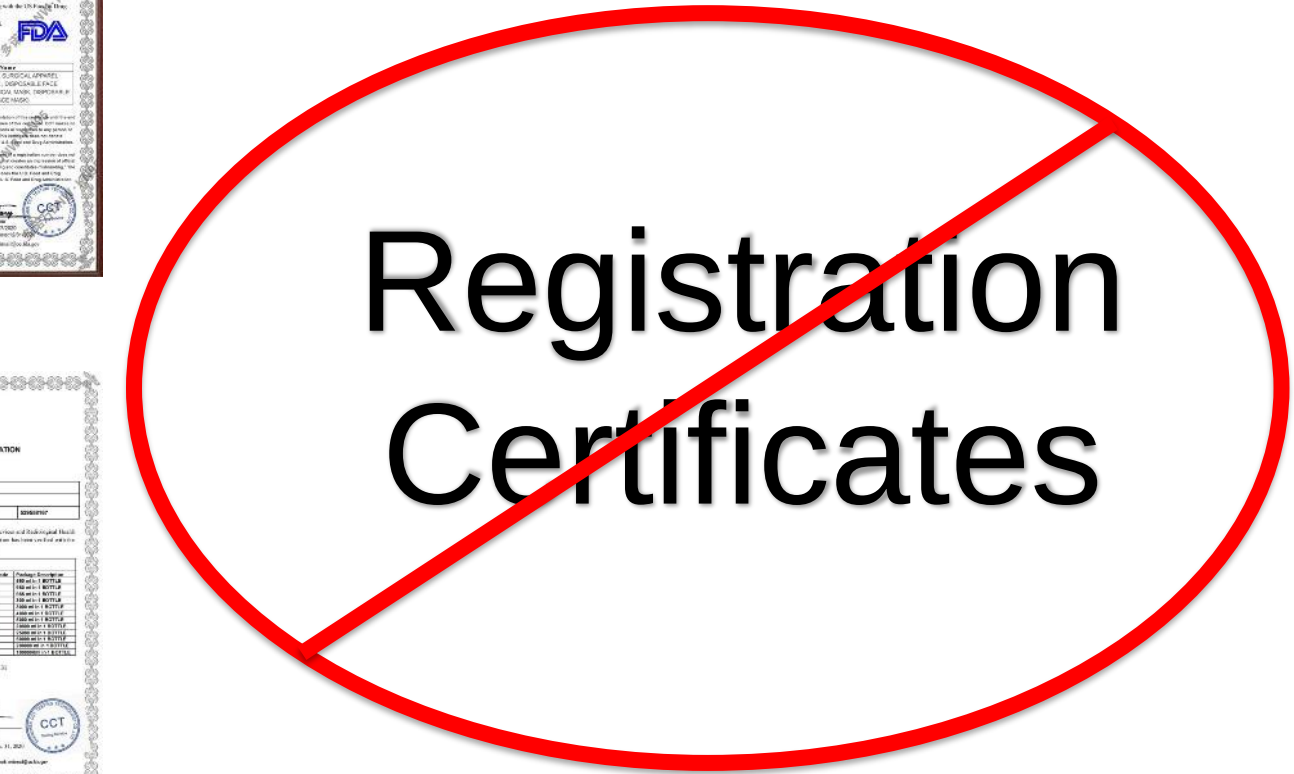
## NOTIFICATIONS

*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

https://direct.fda.gov

# LIVE DEMO
# on
# CDER Direct Continued

Home

## SUBMISSIONS

(ADD SUBMISSION TYPE)

- NDC/NHRIC 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 eDRLS@fda.hhs.gov.

GO ACTIONS

| STATUS | SET ID | ROOT ID | SUBMISSION ID | VERSION | DOCUMENT LABEL | LAST MODIFIED USER | LAST MODIFIED DATE | |
|---|---|---|---|---|---|---|---|---|
| DRAFT | a45ec646-40b8-364c-e053-2a95af0a38e3 | 9985bf0a-da5b-b3e1-e053-2995af0ad64f | - | 3 | HUMAN OTC DRUG LABEL | John Johnson | 15-SEP-2021 21:06:17 | |
| DRAFT | 232bd24d-3719-54dc-e054-00144ffa2cc4 | 232bd24d-371a-54dc-e054-00144ffa2cc4 | - | 1 | WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT | John Johnson | 11-AUG-2021 12:23:14 | |
| DRAFT | fb93b4f6-9eaf-4c35-a110-1f526ca7c373 | c6f025d2-ab31-570e-e053-2995af0afd0a | - | 2 | HUMAN OTC DRUG LABEL | John Johnson | 04-AUG-2021 12:28:11 | |
| DRAFT | 54c681f2-c42c-4f91-8af8-d77f156993f5 | c6f025d2-ab26-570e-e053-2995af0afd0a | - | 2 | HUMAN OTC DRUG LABEL | John Johnson | 12-JUL-2021 11:55:17 | |
| DRAFT | 2823096e-3da4-70ba-e054-00144ff8a759 | 2823096e-3da5-70ba-e054-00144ff8a759 | - | 1 | ESTABLISHMENT REGISTRATION | John Johnson | 09-JUL-2021 15:39:19 | |
| DRAFT | c3514376-7090-5b61-e053-2a95af0afa14 | c3514376-7091-5b61-e053-2a95af0afa14 | - | 1 | HUMAN OTC DRUG LABEL NDC RESERVATION | John Johnson | 28-MAY-2021 09:04:15 | |
| SUBMISSION FAILED | c23d89e9-b00b-4520-e053-2995a90a95af | c2c4917f-2ba3-bc1f-e053-2a95af0a0766 | cd1092583674.7398256041@direct | 2 | HUMAN PRESCRIPTION DRUG LABEL | John Johnson | 20-MAY-2021 10:22:23 | |
| DRAFT | 33394aaa-0817-564e-e054-00144ff8d46c | bf3c8889-fb0b-3866-e053-2995af0adc22 | - | 34 | HUMAN PRESCRIPTION DRUG LABEL | John Johnson | 13-MAY-2021 11:21:50 | |
| DRAFT | 64d33e62-5048-4d3c-9095-84397a8d3fa4 | baeb4372-b513-23c1-e053-2a95af0af699 | - | 3 | HUMAN OTC DRUG LABEL | John Johnson | 13-MAY-2021 11:21:34 | |
| DRAFT | c415b9a8-e518-4389-8fd6-fcf78d92f7b2 | bf42a977-56a4-40c2-e053-2a95af0a9c82 | - | 5 | HUMAN OTC DRUG LABEL | John Johnson | 13-MAY-2021 11:21:16 | |
| DRAFT | 5d68363d-bdbe-608b-e053-2991aa0aa85d | 7cff008e-0165-1197-e053-2a91ab0a058a | - | 4 | HUMAN COMPOUNDED DRUG LABEL | John Johnson | 27-APR-2021 14:57:52 | |
| DRAFT | a3bb2fdf-3f63-1aaa-e053-2995a90ae230 | b66ec446-fcfe-057b-e053-2a95af0a2189 | - | 2 | HUMAN OTC DRUG LABEL | John Johnson | 08-APR-2021 14:02:08 | |
| DRAFT | 83366ae1-e1dc-2a30-e053-2a91aa0a1cc4 | b4f656cc-8a47-8c02-e053-2995af0a7a50 | - | 3 | HUMAN OTC DRUG LABEL | John Johnson | 05-APR-2021 19:06:41 | |
| DRAFT | a51078e0-189c-a2a5-e053-2995a90a4a1c | b82c769c-3d5b-493d-e053-2995af0a6a1f | - | 5 | 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/NHRIC Labeler Code Request
- Establishment Registration
- Product Listing and Certification
- WDD/JPL

## 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-e054-00144ff8a759 | cd7755a7-26fc-4d0d-e053-2a95af0a7608 | - | 2 | 777777777 | Core | ESTABLISHMENT REGISTRATION | DETAILS | John Johnson | 03-OCT-2021 13:44:51 | - |
| SUBMISSION ACCEPTED | 438cd80c-5447-4ac6-e054-00144ff8a759 | 438cd80c-5448-4ac6-e054-00144ff8a759 | cd826731496.1860245973@direct | 1 | 777777777 | Core | ESTABLISHMENT REGISTRATION | DETAILS | John Johnson | 02-OCT-2017 11:00:20 | - |

1 - 2

U.S. FOOD & DRUG ADMINISTRATION

# Thank You for Registering and Re-Registering!

## Contact Us:

eDRLS@fda.hhs.gov


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ADMINISTRATION