**CDER Direct
Establishment Registration
Out of Business Notification**

Establishment Registration
Out of Business Notification

U.S. Department of **Health & Human Services**

CDER *Direct*
Electronic Submissions Portal

Step 1: Log into your CDER Direct Account

LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitio

☐ I Understand.

LOGIN   Forgot your password?

CDER Direct: direct.fda.gov

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SUBMISSIONS
(ADD SUBMISSION TYPE)

NDC/NHRIC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/3PL

ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov

Step 2: Click on Establishment Registration

GO   **ACTION**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
SUBMISSION ACCEPTED	04586534-ac2d-49b1-ba15-4e0c70ee63f3	8bd7f3da-2729-670b-e053-2a95af0aad1f	cd6517423908.285316947@direct	14
SUBMISSION ACCEPTED	04586534-ac2d-49b1-ba15-4e0c70ee63f3	7fa87aa8-2965-5540-e053-2a91ab0a152e	cd529486713.9417560328@direct	13

Step 3: Open the previously submitted and accepted Establishment Registration

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Out of Business Notification

Home › Establishment Registration › SPL Submission

Step 6: Submit SPL → SUBMIT SPL   SAVE AS DRAFT   SAVE AND VALIDATE

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk

— HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION ▾

--Select One--
ESTABLISHMENT REGISTRATION
ESTABLISHMENT DE-REGISTRATION
NO CHANGE NOTIFICATION
OUT OF BUSINESS NOTIFICATION

Set ID: *   Generate New   Version Number: *   27

Root ID: *   Generate New   Effective Date: *   09-23-2022

Step 5: Change the document type to Out of Business Notification

— REGISTRANT DETAILS

Registrant Name: *   Drug Firm

Registrant DUNS: *   012345678

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Establishment Registration – Document Types

- Document Types
  - Establishment Registration
    - *to register or update your establishment(s) information*
  - No change notification
    - *each year when the information is updated, if there is no change*
  - Out of Business
    - *if the registrant goes out of business*
  - Establishment De-Registration
    - *de-register your establishment(s)*

CDER Direct: direct.fda.gov

For more information

Log on to CDER Direct: direct.fda.gov

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

- *Microsoft Edge*
- *Firefox version 28 and above*
- *Google Chrome*
- *Safari 10.0.1 and above*

Help Desk: CDERdirect@fda.hhs.gov