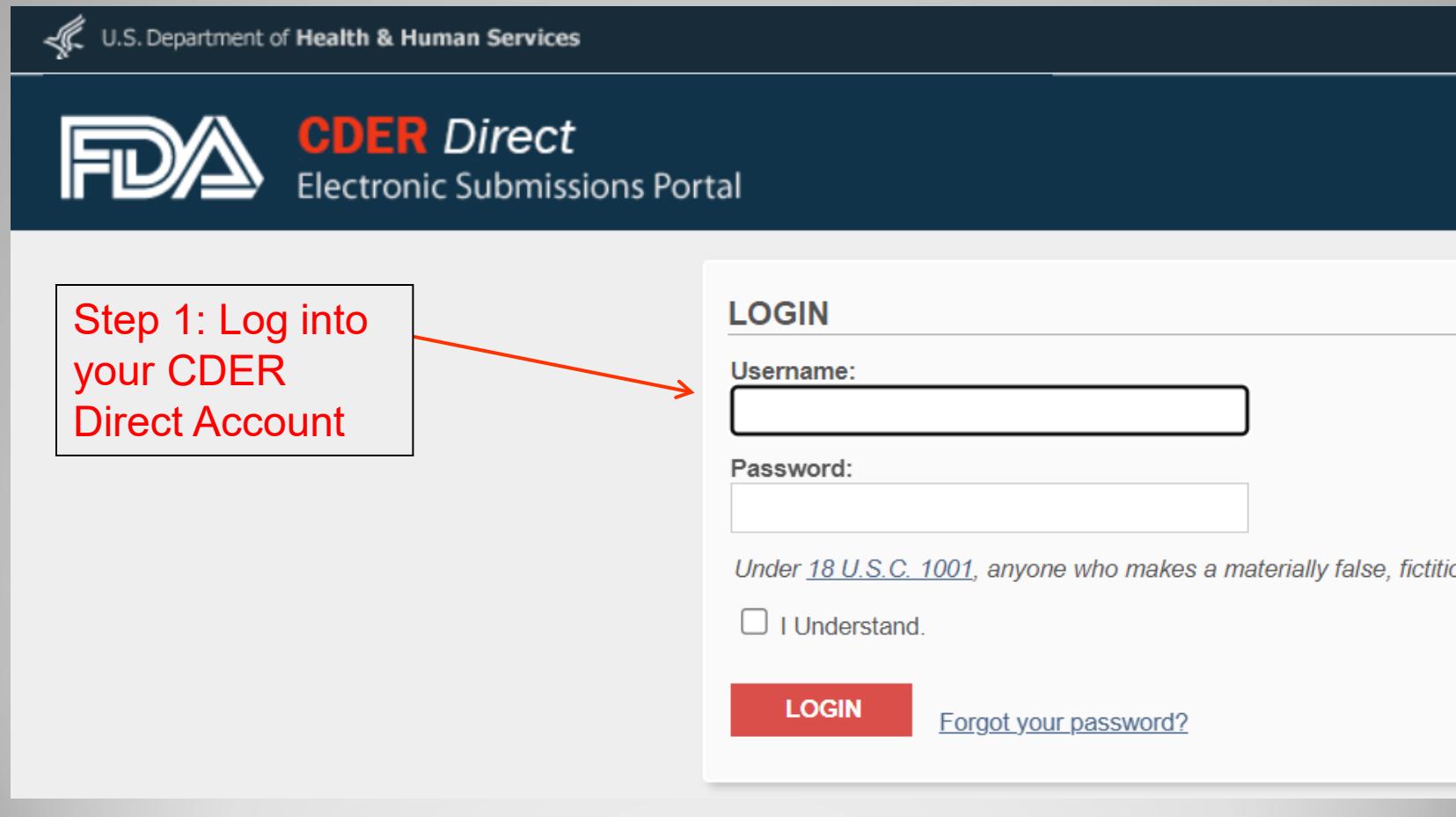




CDER Direct
Electronic Submissions Portal

CDER Direct
Establishment De-Registration

Establishment De-Registration



Step 1: Log into your CDER Direct Account

U.S. Department of Health & Human Services

FDA **CDER Direct**
Electronic Submissions Portal

LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement or representation in any application or document filed or submitted in connection with an application for a drug or biological product subject to the Federal Food, Drug, and Cosmetic Act, or for a medical device subject to the Medical Device Reporting requirement, shall be subject to punishment as provided in section 1001 of such Act.

I Understand.

LOGIN [Forgot your password?](#)

CDER Direct: direct.fda.gov

Establishment De-Registration

SUBMISSIONS (ADD SUBMISSION TYPE)

NDC/NHRIC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/3PL

Step 3: Open the previously submitted and accepted Establishment Registration

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

Establishment De-Registration

Home > Establishment Registration > SPL Submission

VIEW SPL **DOWNLOAD SPL** **CREATE NEW VERSION**

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 indicate required fields.

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

Set ID: * a27c2e3e-b665-c8f3-7a8e-08f5fd7fe5d7 [Generate New](#)

Root ID: * e935a701-0687-a6df-e053-2995af0a33e6 [Generate New](#)

Version Number: * 27

Effective Date: * 09-21-2022 [Calendar](#)

REGISTERANT DETAILS

Registrant Name: * Drug Firm

Registrant DUNS: * 012345678

REGISTERANT CONTACT DETAILS

REGISTERANT CONTACT ADDRESS

Step 4: Click Create New Version

Establishment De-Registration

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

Set ID: * --Select One--
ESTABLISHMENT REGISTRATION
ESTABLISHMENT DE-REGISTRATION
NO CHANGE NOTIFICATION
OUT OF BUSINESS NOTIFICATION

Root ID: * Generate New

Version Number: * 27

Effective Date: * 09-23-2022

REGISTERANT DETAILS

Registrant Name: * Drug Firm

Registrant DUNS: * 012345678

Step 5: Change the document type to Establishment De-Registration

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)*

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