CDER *Direct*
Electronic Submissions Portal

CDER Direct
Establishment De-Registration

Establishment De-Registration
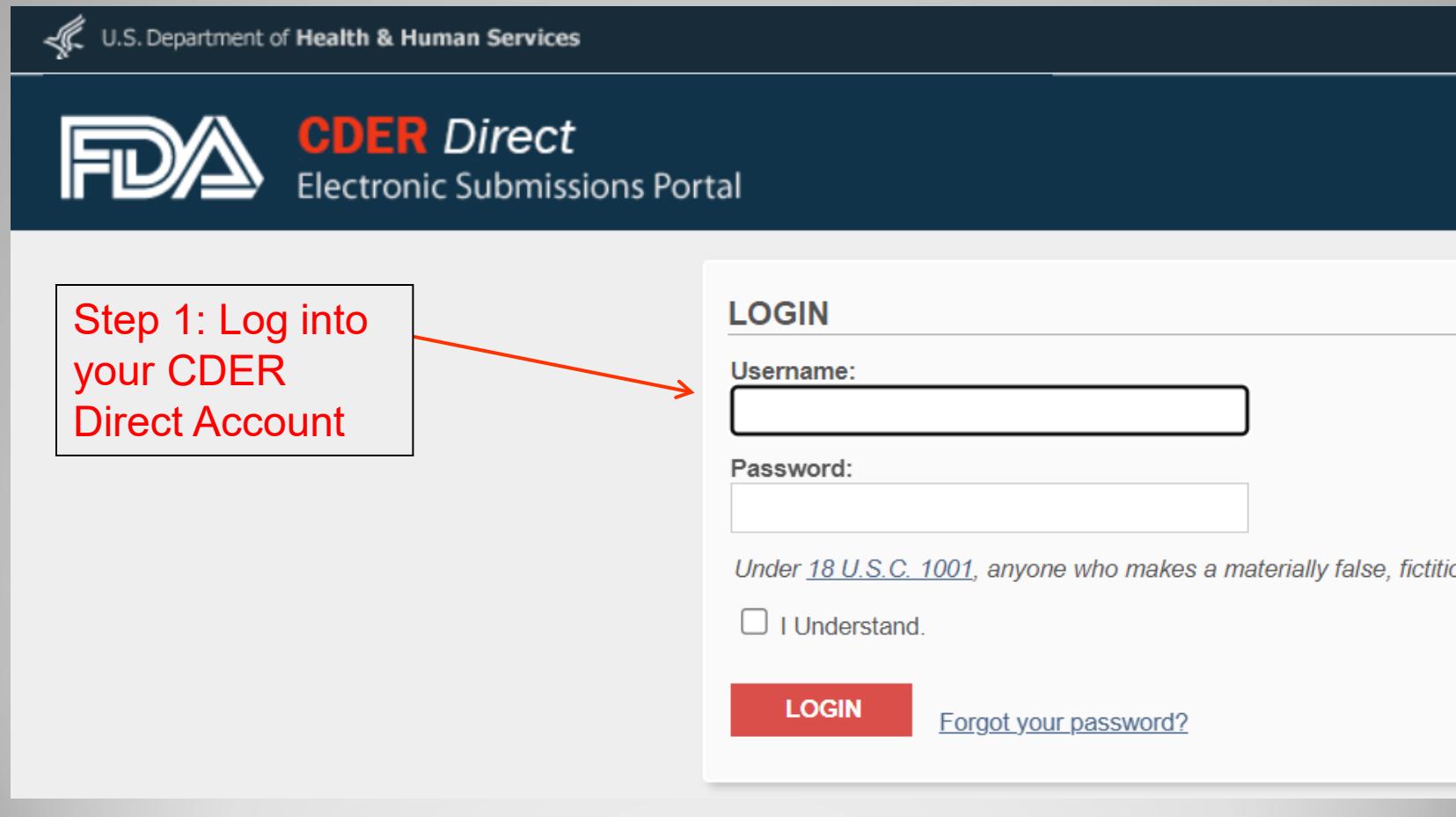
Step 1: Log into your CDER Direct Account

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

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

CDER Direct: direct.fda.gov

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 fiel

Step 4: Click Create
New Version

HEADER DETAILS

Document Type: * [ESTABLISHMENT REGISTRATION ⌄]

Set ID: * [a27c2e3e-b665-c8f3-7a8e-08f5fd7fe5d7] Generate New   Version Number: * [27]

Root ID: * [e935a701-0687-a6df-e053-2995af0a33e6] Generate New   Effective Date: * [09-21-2022] 📅

REGISTRANT DETAILS

Registrant Name: * [Drug Firm]

Registrant DUNS: * [012345678]

REGISTRANT CONTACT DETAILS   **REGISTRANT CONTACT ADDRESS**

CDER Direct: direct.fda.gov

Establishment De-Registration

CDER Direct: direct.fda.gov

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