How to Submit an Establishment Registration

Regie Samuel
Technical Information Specialist
OC/OUDLC/DRLB
CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT
September 28, 2023

Learning Objectives

- Determine who registers and when
- Create and submit an Establishment Registration

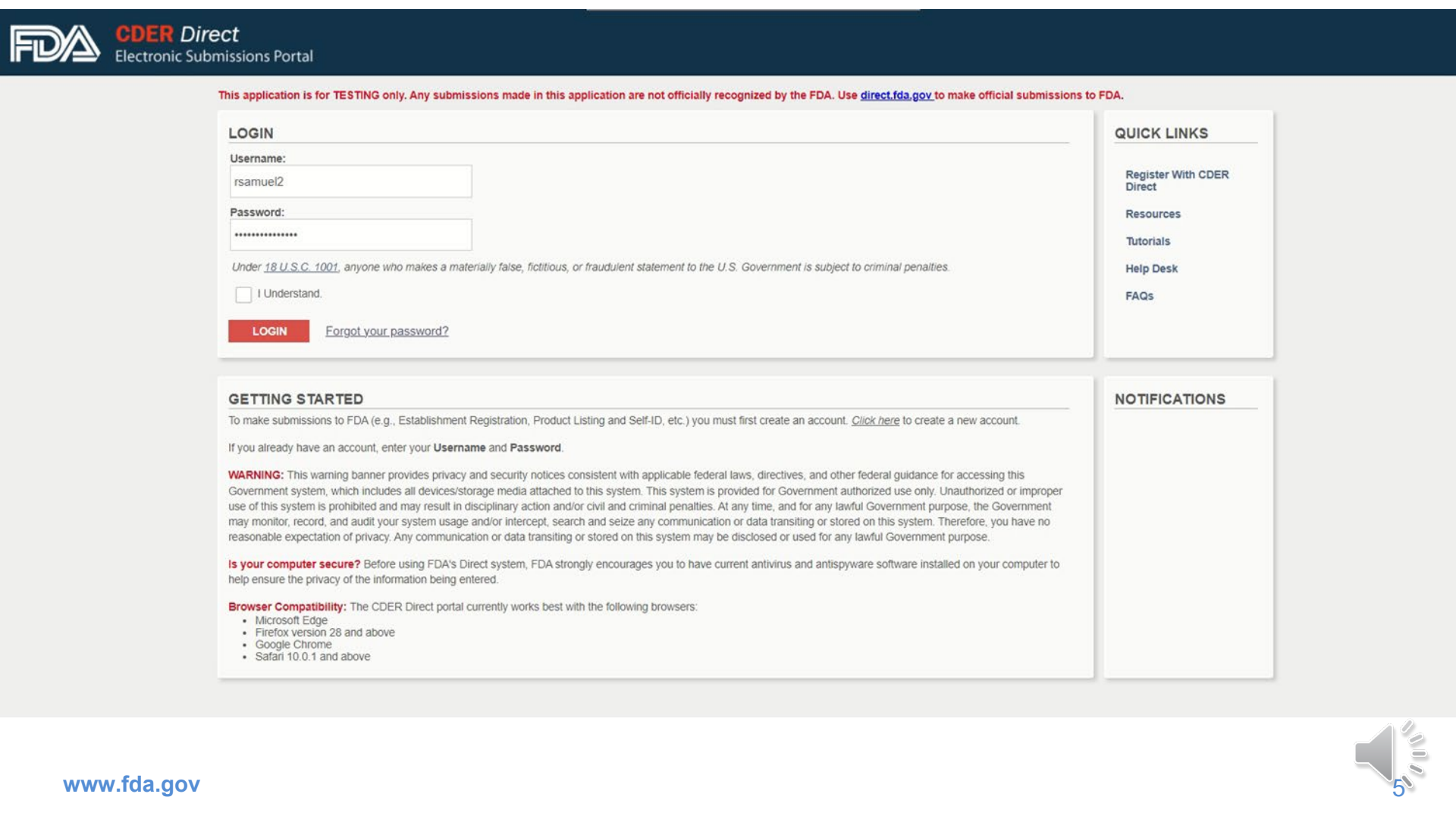
Who Must Register?

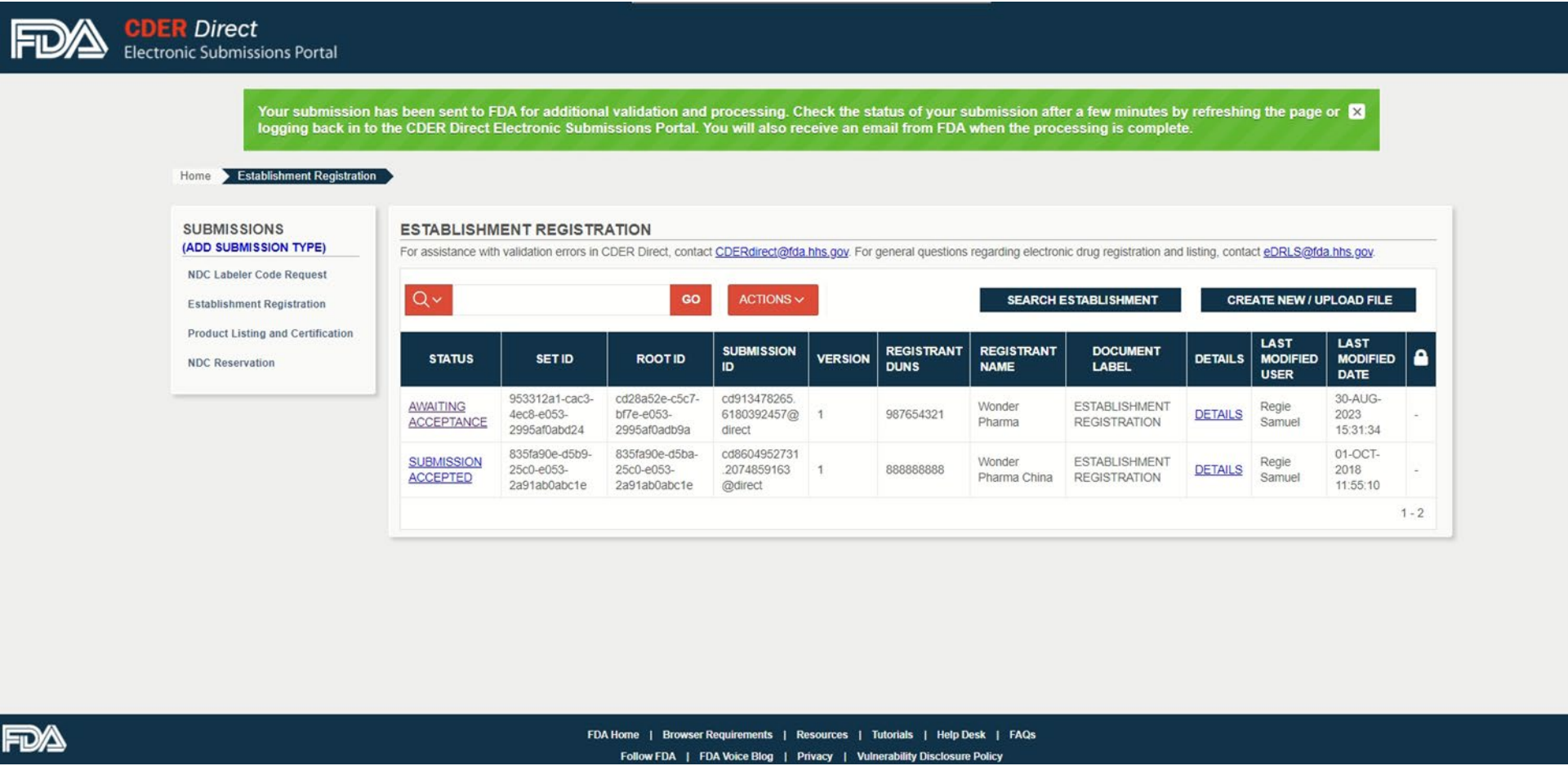
- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the United States (21 CFR 207.17).
- Certain exemptions are included under 21 CFR 207.13.

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.


CDER Direct
Electronic Submissions Portal
This application is for TESTING only. Any submissions made in this application are not officially recognized by the FDA. Use direct.fda.gov to make official submissions to FDA.
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
Register With CDER Direct
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 Edge
Firefox version 28 and above
Google Chrome
Safari 10.0.1 and above
NOTIFICATIONS


CDER Direct
Electronic Submissions Portal
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 Labeler Code Request
Establishment Registration
Product Listing and Certification
NDC Reservation
ESTABLISHMENT REGISTRATION
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
SEARCH ESTABLISHMENT
CREATE NEW / UPLOAD FILE
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
REGISTRANT DUNS
REGISTRANT NAME
DOCUMENT LABEL
DETAILS
LAST MODIFIED USER
LAST MODIFIED DATE
AWAITING ACCEPTANCE
953312a1-cac3-4ec8-e053-2995af0abd24
cd28a52e-c5c7-bf7e-e053-2995af0adb9a
cd913478265.6180392457@direct
1
987654321
Wonder Pharma
ESTABLISHMENT REGISTRATION
DETAILS
Regie Samuel
30-AUG-2023 15:31:34
-
SUBMISSION ACCEPTED
835fa90e-d5b9-25c0-e053-2a91ab0abc1e
835fa90e-d5ba-25c0-e053-2a91ab0abc1e
cd8604952731.2074859163@direct
1
888888888
Wonder Pharma China
ESTABLISHMENT REGISTRATION
DETAILS
Regie Samuel
01-OCT-2018 11:55:10
-
1 - 2
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

Registration Certificates

Challenge Question

Who should not register as a drug establishment?

A. Repackagers

B. Private Label Distributors

C. Contract Manufacturers

D. Manufacturers

Summary

- Register on time – it's easy!
- You can manage multiple establishment locations on one Establishment Registration
- Ensure your DUNS information is up-to-date with D&B
- Firms that are solely Private Label Distributors should not register as a drug establishment

U.S. FOOD & DRUG ADMINISTRATION

Thank You for Registering!

Contact Us:

eDRLS@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION