



CDER *Direct*

Electronic Submissions Portal

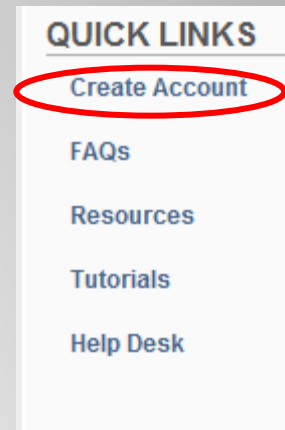
CDER Direct – Quick Start Guide

Accessing the Application

To access CDER Direct, enter direct.fda.gov into IE 8

First Time Users – Select Create Account; enter all the requested user and company information

Activating - Once you click submit, you must activate your account within 48 hours.



Login Screen



CDER Direct

Electronic Submissions Portal

Username or Password entered is incorrect.

LOGIN

Username:

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](#)

[FAQs](#)

[Resources](#)

[Tutorials](#)

[Help Desk](#)

Creating Account

ORGANIZATION INFORMATION

Name: *

DUNS: *

Brief Description: *
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ORGANIZATION ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code:

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

Phone Number: *

Phone Extension:

FORM ACCESS

Labeler Code Request/Activation

NDC LABELER CODE REQUEST

Establishment Annual Registration

ESTABLISHMENT REGISTRATION

GDUFA Facility Self-Identification

GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION

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 have read and agree to the Terms and Conditions stated above.

SUBMIT

CANCEL

Activating Your Account

To activate your account:

1. Open your email account
2. Open the email from cderdirect@fda.gov.
3. Click on the activation link in the email.
4. Enter a user name and password following the guidelines that appear on the screen
5. Select three security questions and enter the answer to each question.
6. Click **Submit**.

(If you do not receive an email, please check your Spam filters)

Activating Your Account

ACTIVATE ACCOUNT

Username must be at least 8 characters and no more than 32 characters. It can consist of any combination of capital and lowercase letters, numbers, a period, or an underscore ("_").

Username: *

Password must be at least 10 characters and no more than 32 characters. It must include a capital letter, a lowercase letter, a number, and a special character.

Password: *

Confirm Password: *

Select and answer security questions. If you forget your password, you will need to provide this information. [Show Answers](#)

Security Question 1: *

Security Answer 1: *

Security Question 2: *

Security Answer 2: *

Security Question 3: *

Security Answer 3: *

SUBMIT

CANCEL

Login Credential Requirements

- Username
 - eight characters including:
 - upper and lower case letters
 - numbers
 - a period or an underscore (“_”)
- Password
 - least ten characters including:
 - an upper and a lower case letter
 - a number
 - a non-alphanumeric character

All forms that you have access to

Using the Home Page

Home

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

MANAGE ACCOUNT

Edit User Profile

Manage Users

- Update profile information
- Manage sub-user accounts

ALL SUBMISSIONS

View all submissions you have access to

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	f2dc6c82-db2b-2468-e044-00144ffaa30a	f32e14dd-b256-6ebf-e044-00144ffaa30a	cd9072581364.3172649085@direct	3	NDC LABELER CODE REQUEST	Jane Doe	26-MAR-2014 18:19:02
DRAFT	f5884a77-08a7-476a-e044-00144ffaa30a	f5884a77-08a8-476a-e044-00144ffaa30a	-	1	ESTABLISHMENT REGISTRATION	Jane Doe	26-MAR-2014 17:22:25
SUBMISSION SUCCESSFUL	f3f58480-b65e-74f4-e044-00144ffaa30a	f3f58480-b65f-74f4-e044-00144ffaa30a	cd2153768490.2795610843@direct	1	ESTABLISHMENT REGISTRATION	Jane Doe	18-MAR-2014 15:02:16
SUBMISSION SUCCESSFUL	f4461a3a-a4c9-3551-e044-00144ffaa30a	f4461a3a-a4ca-3551-e044-00144ffaa30a	cd8532764901.4872951603@direct	1	GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION	Jane Doe	18-MAR-2014 15:02:16

Where do I get more information?

Log on to CDER Direct: direct.fda.gov

Compatible with the following browsers:

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

Help Desk: CDERdirect@fda.hhs.gov