



CDER *Direct*

Electronic Submissions Portal

**CDER Direct –
Establishment Registration
To Update Establishment Information**

Establishment Registration To Update Establishment Information

 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, fictitious

I Understand.

LOGIN

[Forgot your password?](#)

CDER Direct: direct.fda.gov

Establishment Registration To Update Establishment Information

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

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Establishment Registration To Update Establishment Information

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 field

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



Step 4: Click
Create New
Version

REGISTRANT DETAILS

Registrant Name: *

Drug Firm

Registrant DUNS: *

012345678

REGISTRANT CONTACT DETAILS

REGISTRANT CONTACT ADDRESS

CDER Direct: direct.fda.gov

Establishment Registration To Update Establishment Information

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

Step 5: Update any
information as needed

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code:

Establishment Registration To Update Establishment Information

Home Establishment Registration SPL Submission 

SUBMIT SPL

SAVE AS DRAFT

SAVE AND VALIDATE

DELETE

<< RETURN

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](#)

Version Number: * 27

Root ID: * e935e9e1-fa75-547b-e053-2a95af0ab2ca [Generate New](#)

Effective Date: * 09-21-2022 

REGISTRANT DETAILS

Registrant Name: * Durg Firm

Registrant DUNS: * 123456789

REGISTRANT CONTACT DETAILS

Contact Name: * John Doe

Contact Email: * johndoe@gmail.com

Contact Phone: * 1-222-222-2222 [Format](#)

Phone Extension: *

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 1234 Street

City: * Gaithersburg

State: * Maryland

Postal Code: * 20878

Step 6: Click here to update establishment information

ESTABLISHMENTS

ADD ESTABLISHMENT

row(s) 1 - 2 of 2

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	012345678	-	Drug Firm A
	987654321	1234567899	Firm B

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Establishment Registration To Update Establishment Information

Home > Establishment Registration > SPL Submission > Establishment

SAVE ESTABLISHMENT DELETE ESTABLISHMENT << RETURN

Step 7 :
Update any
information as
needed

ESTABLISHMENT DETAILS

Establishment Name: * Drug Firm A

Establishment DUNS: * 012345678

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: * United States

Street Address: * 12345 Street A

City: * Rockville

State: * Maryland

Postal Code: * 123456

ESTABLISHMENT CONTACT DETAILS

Add Registrant Contact Details and Address

Contact Name: * John Doe

Contact Email: * johndoe@gmail.com

Contact Phone: * 1-222-222-2222 [Format](#)

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: * United States

Street Address: * 1234 Street

City: * Gaithersburg

State: * Maryland

Postal Code: * 20878

Note: Enter one or more of the manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

BUSINESS OPERATION(S)

BUSINESS OPERATION	QUALIFIER
✘ MANUFACTURE	MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS
✘ REPACK	MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS

Establishment Registration To Update Establishment Information

Home

Establishment Registration

SPL Submission

Establishment

ESTABLISHMENT DETAILS

Establishment Name: *

Firm B

Establishment DUNS: *

987654321

Establishment FEI: *

Step 9 : The FEI number is required after initial registration. If your firm has previously obtained an FEI number, you may enter the number here.

Establishment Registration

To Update Establishment Information

Home > Establishment Registration > SPL Submission > Establishment

Step 10: Click here to save Establishment information before returning to the previous screen

SAVE ESTABLISHMENT

DELETE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI: *

ESTABLISHMENT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

Establishment Registration To Update Establishment Information

Establishment information saved.

Home > Establishment Registration > SPL Submission



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 indicates required field.

Step 11: Submit SPL

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

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

Version Number: * 27

Root ID: * e935e9e1-fa75-547b-e053-2a95af0ab2ca [Generate New](#)

Effective Date: * 09-21-2022

REGISTRANT DETAILS

Registrant Name: * Durg Firm

Registrant DUNS: * 123456789

CDER Direct: direct.fda.gov

Establishment Registration – Document Types

Document Types

- Establishment Registration
 - *to register your establishment(s)*
- 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
Compatible 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