

Establishment De-Registration

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CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT
October 8, 2020

Learning Objectives

- Importance of De-Registration
- When to De-Register
- De-Registration Document Types
- Demo of CDER Direct
- Challenge Question

Importance of De-Registration



- Preserve integrity of the system when companies are no longer manufacturing
- Assists the agency in inspection planning
 - Rely on database for internal and external programs
- Alerts business partners when changes are made



When to De-Register

- Expedited registration updates to be provided within 30 calendar days of a change (21 CFR 207.29)

Document Types for Establishment De-Registration



- Establishment De-Registration SPL
- Out of Business Notification SPL

Establishment De-Registration SPL

- De-register because the firm is no longer manufacturing drug products for commercial distribution in the US



Out of Business Notification SPL



- Firm is no longer in business



<https://direct.fda.gov>

DEMO of CDER Direct



SUBMISSION ACCEPTED	991ab0a2efc	ab0a2efc					REGISTRATION	
	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION	D
	374-5505-0054	374-5505-0055-0						

Home Establishment Registration **SPL Submission**

VIEW SPL

DOWNLOAD SPL

CREATE NEW VERSION

<< 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. Asterisk indicate required fields.

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION ▼

Set ID: * 438cd80c-5447-4ac6-e054-00144ff8a759

Version Number: * 1

[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: * 438cd80c-5447-4ac6-e054-00144ff8a759 [Generate New](#)

Version Number: * 2

Root ID: * 7c34d527-672d-d083-e053-2991ab0abfad [Generate New](#)

Effective Date: * 09-15-2020

[SUBMIT SPL](#)
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**SUBMIT SPL**

SAVE AS DRAFT

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 DE-REGISTRATION ▼

Set ID: * 438cd80c-5447-4ac6-e054-00144ff8a759 [Generate New](#)

Version Number: * 2

Root ID: * 7c34d527-672d-d083-e053-2991ab0abfad [Generate New](#)

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SUBMIT SPL

SAVE AS DRAFT

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: * OUT OF BUSINESS NOTIFICATION ▼

Set ID: * 438cd80c-5447-4ac6-e054-00144ff8a759 [Generate New](#)

Version Number: * 2

Root ID: * 7c34d527-672d-d083-e053-2991ab0abfad [Generate New](#)

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Document Type: * ESTABLISHMENT REGISTRATION

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Version Number: * 2

Root ID: * 7c34d527-672d-d083-e053-2991ab0abfad [Generate New](#)

Effective Date: * 09-15-2020

REGISTRANT DETAILS

Registrant Name: * Core

Registrant DUNS: * 77777777

REGISTRANT CONTACT DETAILS

Contact Name: * Troy

Contact Email: * troy@email.com

Contact Phone: * 555-555-5555 [Format](#)

Phone Extension: *

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 123 FDA Drive

City: * DRLS

State: * Maryland

Postal Code: * 20904

ESTABLISHMENTS

ADD ESTABLISHMENT

row(s) 1 - 2 of 2

	ESTABLISHMENT DUNS	ESTABLISHMENT EEL	ESTABLISHMENT NAME
	987654321	-	Core7
	123456781	-	Test

SAVE ESTABLISHMENT

DELETE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: *

Street Address: *

City: *

State: *

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: *

Phone Extension:

[Format](#)

City: *

State: *

Message from webpage



Are you sure you want to delete the Establishment?

OK

Cancel

Note: Enter the one or more drug 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 PRODUCED UNDER A MON

[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: * 438cd80c-5447-4ac8-e054-00144ff8a759 [Generate New](#)

Version Number: *

Root ID: * 7c34d527-672d-d083-e053-2991ab0abfad [Generate New](#)

Effective Date: *

== REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: *

Street Address: *


City: *

State: *

Postal Code: *

== ESTABLISHMENTS

[ADD ESTABLISHMENT](#)

ESTABLISHMENT ID	ESTABLISHMENT TYPE	ESTABLISHMENT NAME
 987654321	-	Core7



Challenge Question

How do I de-register one of the three establishments on my Establishment Registration SPL?

- A. Submit an Establishment De-Registration SPL
- B. Submit an Out of Business Notification SPL
- C. Delete the entire Establishment Registration SPL from CDER Direct
- D. Delete the particular Establishment I want to de-register from the Establishment Registration SPL and submit

Summary

- De-register on time – it's easy!
- Submit an Establishment De-Registration or an Out of Business Notification SPL to de-register all Establishments in an Establishment Registration
- Do not submit an Establishment De-Registration or Out of Business Notification to de-register only one of many establishments

Thank You for De-Registering!

Contact Us:

eDRLS@fda.hhs.gov

