

How to Submit an Establishment Registration

Regie Samuel

Technical Information Specialist

OC/OPRO/DRLS

CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT

October 8, 2020

Learning Objectives

- Establishment Registration
 - Who, When, How
- Live Demo
- Challenge Questions



Who Must Register?

- Any establishment that manufactures, repackages, relabels, or salvages drugs for distribution in the U.S.
- Certain exemptions are listed on the [eDRLS website](#).

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.



<https://direct.fda.gov>

LIVE DEMO
on
CDER Direct



COVID-19 Update - As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product obtained after logging in. (Not applicable to 503B outsourcing or compounding facilities)

LOGIN

Username:

test1

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?](#)



Home

SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC/NHRIC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDDOPL

ALL SUBMISSIONS

For help with your SPL submission, contact CDERdirect@fda.hhs.gov. For questions related to Drug Establishment Registration and Product Listing, contact eDRLS@fda.hhs.gov.



GO

ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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SUBMISSIONS
[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDD/3PL

ESTABLISHMENT REGISTRATION

For help with your SPL submission, contact CDERdirect@fda.hhs.gov. For questions related to Drug Establishment Registration and Product 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	
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SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRIC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDD/3PL

CREATE NEW ESTABLISHMENT REGISTRATION

- ☒ Create New Establishment Registration using a blank form
- ☐ Import an existing Establishment Registration SPL

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE

CANCEL

SAVE AS DRAFT

<< 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: * --Select One-- 

Set ID: * af5cd31c-9f44-067d-e053-2995af0aac27 [Generate New](#)

Version Number: *

Root ID: * af5cd31c-9f45-067d-e053-2995af0aac27 [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: * --Select Country-- 

Street Address: * 

City: *

State/Province:

Postal Code:

— HEADER DETAILS

Document Type: *

—Select One—

ESTABLISHMENT REGISTRATION

ESTABLISHMENT DE-REGISTRATION

OUT OF BUSINESS NOTIFICATION

[Generate New](#)

Set ID: *

Version Number: *

1

Root ID: *

af5cd31c-9f45-067d-e053-2995af0aac27

[Generate New](#)

Effective Date: *

09-15-2020



— REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: *

Phone Extension:

[Format](#)

REGISTRANT CONTACT ADDRESS

Country: *

—Select Country—

Street Address: *

City: *

State/Province:



Registrant Name:



The registrant is the owner or operator of an establishment that manufactures a drug. The registrant is the official contact for establishment registrations. Facility contacts, if different from the registrant, should be entered under 'Establishments'.

REGISTRANT DETAILS

Registrant Name: *

Core

Registrant DUNS: *

77777777

REGISTRANT CONTACT DETAILS

Contact Name: *

Troy

Contact Email: *

troy@email.com

Contact Phone: *

1-555-555-5555



[Format](#)

Phone Extension:

Street Address: *

123 FDA Drive

City: *

DRLS

State: *

Maryland

Postal Code: *

20904



— 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 DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: * ▼

Street Address: *

City: *

State/Province:

Postal Code:

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: * ▼

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

Phone Extension:

ESTABLISHMENT ADDRESS

Country: *

Street Address: *

City: *

State/Province:

Postal Code: * X

ESTABLISHMENT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI: *

ESTABLISHMENT ADDRESS

Country: *

Street Address: *

City: *

State/Province:

Postal Code: *

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

Phone Extension:

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

ESTABLISHMENT ADDRESS

Country: *

Street Address: *

City: *

State/Province:

Postal Code: * X

ESTABLISHMENT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

Phone Extension:

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

Phone Extension:

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.

IMPORTERS IMPORTERS

+		+	NAME	DUNS	PHONE	EXTENSION
✗	Button	✗	--Select One--		789-456-1234	
			HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY			
			ANALYSIS			
			MANUFACTURE			
			REPACK			
			RELABEL			
			API MANUFACTURE			
			STERILIZE			
			MEDICATED ANIMAL FEED MANUFACTURE			
			PACK			
			LABEL			
			OUTSOURCING ANIMAL DRUG COMPOUNDING			
			TRANSFILL			

BUSINESS OPI	BUSI	QUALIFIER
✗	MANUFA	AN PRESCRIPTION DRUG PRODUCTS
✗	MANUFA	AN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MON
✗	REPACK	AN OVER-THE-COUNTER DRUG PRODUCTS NOT PRODUCED UNDER A

U.S. AGENT

Agent Name: *	<input type="text" value="Reg"/>
Agent DUNS: *	<input type="text" value="888888888"/>
Agent Email: *	<input type="text" value="reg@email.com"/>
Agent Phone: *	<input type="text" value="1-666-666-666"/> Format
Phone Extension:	<input type="text"/>

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.

IMPORTERS

+					
--Select One--					
MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS					
MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS					
MANUFACTURES VETERINARY FEED DIRECTIVE TYPE A MEDICATED ARTICLE DRUG PRODUCTS					
MANUFACTURES ANIMAL OVER-THE-COUNTER DRUG PRODUCTS					
TRANSFILLS MEDICAL GAS					
MANUFACTURES ANIMAL PRESCRIPTION DRUG PRODUCTS					
MANUFACTURES ANIMAL OVER-THE-COUNTER TYPE A MEDICATED ARTICLE DRUG PRODUCTS					
MANUFACTURES NON-GENERIC					
MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH					
MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER AN APPROVED DRUG APPLICATION					
MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NOT PRODUCED UNDER AN APPROVED DRUG APPLICATION OR UNDER A MONOGRAPH					
✕	REPACK	▼	MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NOT PRODUCED UNDER A ▼		

SAVE ESTABLISHMENT

DELETE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name:

Establishment DUNS:

Establishment FEI:

ESTABLISHMENT ADDRESS

Country:

Street Address:

City:

State/Province:

Postal Code:

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name:

Contact Email:

Contact Phone:

Phone Extension:

[Format](#)

ESTABLISHMENT CONTACT ADDRESS

Country:

Street Address:

City:

State:

Postal Code:

— HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION ▼

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

Version Number: * 1

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 FEI	ESTABLISHMENT NAME
	987654321	-	Core7

— HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION ▼

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

Version Number: * 1

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 FEI	ESTABLISHMENT NAME
	987654321	-	Core7
	123456781	-	Test

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**

ALL SUBMISSIONS

For help with your SPL submission, contact CDERdirect@fda.hhs.gov. For questions rel



[GO](#)
[ACTION](#)

STATUS	SET ID	ROOT ID	SUBMISSION ID
DRAFT	438cd80c-5447-4ac6-e054-00144ff8a759	7c34d527-672d-d083-e053-2991ab0abfad	-

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: *

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](#)

REGISTRANT CONTACT ADDRESS

Country: *

Street Address: *

City: *

SUBMISSION FAILED

SUBMISSION ACCEPTED	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION
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A large red oval with a diagonal slash through it, centered over the text "Registration Certificates".

**Registration
Certificates**

Establishment Registration Renewal

Regie Samuel

Technical Information Specialist

OC/OPRO/DRLS

CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT

October 8, 2020

Learning Objectives

- Establishment Re-Registration
 - When & How
- Live Demo
- Challenge Questions



When to Update Your Registration



- Annual registration renewal to be submitted between Oct. 1 and Dec. 31
- Expedited updates to be provided within 30 days of a change
 - Closing or selling an establishment (De-Registration)
 - Changing an establishment's name or physical address
 - Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent.

Document Types for Establishment Renewal



- Establishment Registration
- No Change Notification



<https://direct.fda.gov>

LIVE DEMO
on
CDER Direct



Home

SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC/NHRIC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDDOPL

ALL SUBMISSIONS

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GO

ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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SUBMISSION ACCEPTED	991ab0a2efc	ab0a2efc					REGISTRATION	
	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION	D
	274-5505-0054	274-5505-0055-0						

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. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION ▼

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

Version Number: * 1



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

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 FEI	ESTABLISHMENT NAME
	987654321	-	Core7
	123456781	-	Test

— HEADER DETAILS

Document Type: *

--Select One--
ESTABLISHMENT REGISTRATION
ESTABLISHMENT DE-REGISTRATION
NO CHANGE NOTIFICATION
OUT OF BUSINESS NOTIFICATION

Set ID: *

271e5f9f-96b4-0d5a-e054-00144ff8a759

[Generate New](#)

Version Number: *

1

— 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 FEI	ESTABLISHMENT NAME
	987654321	-	Core7
	123456781	-	Test

— HEADER DETAILS

Document Type: *

--Select One--
ESTABLISHMENT REGISTRATION
ESTABLISHMENT DE-REGISTRATION
NO CHANGE NOTIFICATION
OUT OF BUSINESS NOTIFICATION

Set ID: *

271e5f9f-96b4-0d5a-e054-00144ff8a759

[Generate New](#)

Version Number: *

1

— 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 FEI	ESTABLISHMENT NAME
	987654321	-	Core7
	123456781	-	Test



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 

REGISTRANT DETAILS

Registrant Name: * Core



SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRC Labeler Code Request
- Establishment Registration
- Product Listing and Certification
- WDD/3PL

ESTABLISHMENT REGISTRATION

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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	
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SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRIC Labeler Code Request

Establishment Registration

Product Listing and Certification

WDD/3PL

CREATE NEW ESTABLISHMENT REGISTRATION

- ☐ Create New Establishment Registration using a blank form
- ☒ Import an existing Establishment Registration SPL

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSION AC Dashboard.

CONTINUE

CANCEL

SUBMISSIONS

(ADD SUBMISSION TYPE)

- NDC/NHRC Labeler Code Request
- Establishment Registration
- Product Listing and Certification
- WDD/3PL

This PC > Desktop

New folder

Name	Date modified	Type
ab99b908-605e-7b8c-e...	9/10/2020 2:53 PM	Compressed (zipp...
ab829364-b3c8-978a-e...	8/19/2020 11:15 A...	Compressed (zipp...
ac87d589-644e-8c8e-e...	8/19/2020 1:49 PM	Compressed (zipp...
acd8cde8-7330-e581-e...	8/19/2020 1:48 PM	Compressed (zipp...

FILE

Browse...

e name as the root id followed

SUBMISSIONS

(ADD SUBMISSION TYPE)

- NDC/NHRC Labeler Code Request
- Establishment Registration
- Product Listing and Certification
- WDD/3PL

UPLOAD ESTABLISHMENT REGISTRATION FILE

Establishment Registration File

Note: Please upload a zip file that contains the SPL file with the name as the root id followed I whose names end in '.jpg'.

[SUBMIT SPL](#)[SAVE AS DRAFT](#)[SAVE AND VALIDATE](#)[DELETE](#)[<< RETURN](#)**FDA**

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: * af5e5bc9-fe80-08ba-e053-2995af0a009e [Generate New](#)

Root ID: * af5e5b58-ef08-009b-e053-2995af0a0739 [Generate New](#)

Version Number: * 14

Effective Date: * 09-15-2020

— REGISTRANT DETAILS

Registrant Name: * Uploaded information

Registrant DUNS: * 123456789

REGISTRANT CONTACT DETAILS

Contact Name: * Regie Samuel

Contact Email: * fda@fda.hhs.gov

Contact Phone: * 1-301-111-1111

Phone Extension: *

[Format](#)

REGISTRANT CONTACT ADDRESS

Country: * United States ▼

Street Address: * 123 FDA Drive

City: * Silver Spring

State: * Maryland ▼

Postal Code: * 20904

— ESTABLISHMENTS

[ADD ESTABLISHMENT](#)

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	123456788	-	Uploaded Establishment

Challenge Question #1

Who should not register as a drug establishment?

- A. Repackagers
- B. Contract Manufacturers
- C. Private Label Distributors
- D. Manufacturers



Challenge Question #2

If I submitted my establishment re-registration on September 30, 2020, until what date is my registration current?

- A. October 1, 2020
- B. December 31, 2020
- C. September 30, 2021
- D. December 31, 2021



Summary

- Register and re-register on time – it's easy!
- Ensure your DUNS information is up-to-date with D&B
- Provide accurate contact information
- You can manage multiple establishment locations on one Establishment Registration
- If contact information changes, update your Establishment Registration no later than 30 days from the change

**Thank You for
Registering and Re-Registering!**

Contact Us:
eDRLS@fda.hhs.gov

