

Reference Guide: Drug Establishment Registration

Welcome to Drug Establishment Registration in the FDA Direct Portal

This guide provides the essential information you need to register, re-register, or de-register a drug establishment via FDA Direct.

For technical support, email the eDRLS Help Desk at CDERdirect@fda.hhs.gov.

FDA Direct
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

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LOGIN

OR

CREATE NEW ACCOUNT

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WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct
CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct
On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.
Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic product manufacturers/processors and cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

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Click [here](#) to access the FDA Direct Portal

Registering an Establishment	<u>3</u>
Re-registering or Updating an Establishment	<u>13</u>
Re-registering via No Change Notification	<u>18</u>
De-Registering an Establishment	<u>23</u>
Uploading an Establishment Registration SPL File	<u>30</u>
Assistance with Errors	<u>34</u>

Registering an Establishment

Registering an Establishment

Step 1 Navigate to FDA Direct by accessing: <https://direct.fda.gov>

Step 2 Enter your login credentials, accept the terms of service, and click **Login**

FDA Direct
CDER Direct & Cosmetics Direct

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This free tool allows you to create and submit your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic manufacturers and products in the marketplace.

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Registering an Establishment

Step 3

Click on **Establishment Registration**

Step 4

Click on **Create New/Upload File**

ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov.

- Under section 510 of the Act, and 21 CFR 207, with some limited exceptions, firms that manufacture, prepare, propagate, compound, or process drugs in the United States or that are offered for import into the U.S. must be registered with the FDA, see 21 U.S.C. 360(b), (c), (d), and (i).
- Firms that are solely Private Label Distributors (PLDs) who are not involved in the manufacturing process, as outlined above, should not register as a drug establishment via Establishment Registration SPL.
- After receiving a successful submission, indicated by "Submission Accepted," the establishment's information will appear on the [Drug Establishment Current Registration Site \(DECRS\)](#) within 1-2 business days.
- Establishment registrations submitted during the October 1 to December 31 period are considered registered until the end of following calendar year. Any registration submission received outside of this timeframe does not extend the registration expiration date beyond the current calendar year.
- Establishment registrations and drug listing requirements and submissions are different than device registration and listing, WDD/3PL registration, 503B facility registration and product reporting, cosmetics registration and listing, and GDUFA Self-ID submissions. Please contact the respective FDA center and office for questions on these separate requirements, if applicable.

Registering an Establishment

Step 5

Click on **Create a New Establishment Registration using a blank form** and then click **Continue**

The screenshot shows the 'CREATE NEW ESTABLISHMENT REGISTRATION' page. On the left, there are two main menu sections: 'ESTABLISHMENT REGISTRATION & DRUG LISTING' and 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING'. Under the first section, there are four options: 'Establishment Registration', 'NDC Labeler Code Request', 'Drug Listing and Certification', and 'NDC Reservation'. The 'Establishment Registration' option is selected. In the main content area, there are two radio buttons: 'Create New Establishment Registration using a blank form' (which is selected and highlighted with a red box) and 'Import an existing Establishment Registration SPL'. Below these is a note: '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.' At the bottom, there are two buttons: 'CONTINUE' (in red) and 'CANCEL' (in grey).

Step 6

In the Document Type drop-down menu, select **Establishment Registration**

The other information under Header Details (Set ID, Root ID, Version Number, Effective Date) will be automatically populated

NOTE: Effective Date is not associated with the date the SPL is effective. The date an SPL is received is considered the date it is effective

The screenshot shows the 'SPL Submission' form. At the top, there are navigation links: 'All Submissions', 'Establishment Registration', and 'SPL Submission'. There are two buttons: 'SAVE AS DRAFT' (in red) and '<< RETURN' (in grey). A note reads: '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.' The form is divided into two sections: 'HEADER DETAILS' and 'REGISTRANT DETAILS'. In the 'HEADER DETAILS' section, the 'Document Type' dropdown menu is open, showing options: '--Select One--', 'ESTABLISHMENT REGISTRATION', 'ESTABLISHMENT DE-REGISTRATION', 'NO CHANGE NOTIFICATION', and 'OUT OF BUSINESS NOTIFICATION'. The 'ESTABLISHMENT REGISTRATION' option is highlighted. Other fields in this section include 'Set ID', 'Root ID', 'Version Number' (with value 1), and 'Effective Date' (with value 11-27-2023). The 'REGISTRANT DETAILS' section includes fields for 'Registrant Name', 'Registrant DUNS', 'REGISTRANT CONTACT DETAILS' (with 'Contact Name' field), and 'REGISTRANT CONTACT ADDRESS' (with 'Country' dropdown menu).

Registering an Establishment

Step 7

Enter the information for Registrant Details

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

<p>REGISTRANT CONTACT DETAILS</p> <p><u>Contact Name</u>: * <input type="text"/></p> <p><u>Contact Email</u>: * <input type="text"/></p> <p><u>Contact Phone</u>: * <input type="text"/> Format</p> <p><u>Phone Extension</u>: <input type="text"/></p>	<p>REGISTRANT CONTACT ADDRESS</p> <p><u>Country</u>: * <input type="text" value="-Select Country-"/></p> <p><u>Street Address</u>: * <input type="text"/></p> <p><u>City</u>: * <input type="text"/></p> <p><u>State/Province</u>: <input type="text"/></p> <p><u>Postal Code</u>: <input type="text"/></p>
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Quick Tip!

Clicking on a fieldname that has a dotted underline will bring up Help Text to provide more information as to the type of information being requested

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

<p>REGISTRANT CONTACT DETAILS</p> <p><u>Contact Name</u>: * <input type="text"/></p> <p><u>Contact Email</u>: * <input type="text"/></p> <p><u>Contact Phone</u>: * <input type="text"/></p> <p><u>Phone Extension</u>: <input type="text"/></p>	<p>REGISTRANT CONTACT ADDRESS</p> <p><u>Country</u>: * <input type="text" value="select Country-"/></p> <p><u>Street Address</u>: * <input type="text"/></p> <p><u>City</u>: * <input type="text"/></p> <p><u>State/Province</u>: <input type="text"/></p> <p><u>Postal Code</u>: <input type="text"/></p>
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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'.

Registering an Establishment

Step 8

Click on **Add Establishment**

ESTABLISHMENTS
None

ADD ESTABLISHMENT

Step 9

Enter the information for Establishment Details*

NOTE: Ensure that the Establishment Name and Establishment Address exactly match what is in the DUNS record. The Establishment Contact Address does not need to match the DUNS record address

ESTABLISHMENT DETAILS	ESTABLISHMENT ADDRESS
Establishment Name: *	Country: * -Select Country- v
Establishment DUNS: *	Street Address: *
Establishment FEI: *	City: *
<i>*In the initial registration, Establishment FEI can remain blank as it will only be assigned several weeks AFTER registration</i>	State/Province:
	Postal Code:
ESTABLISHMENT CONTACT DETAILS	ESTABLISHMENT CONTACT ADDRESS
<input type="checkbox"/> Same as Registrant Contact Details and Address	Country: * -Select Country- v
Contact Name: *	Street Address: *
Contact Email: *	City: *
Contact Phone: * Format	State/Province:
Phone Extension:	Postal Code:

Registering an Establishment

Step 10a

If the Establishment is located outside of the United States, enter the US Agent information

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * [Format](#)

Phone Extension:

Step 10b

If the Establishment is located out of the United States, click on **Add Importer** to enter Importer information

NOTE: US Agent and Importer information is only required for an Establishment located outside of the United States

IMPORTERS ADD IMPORTER

Postal Code:

Importer ✕

Importer Name: *

Importer DUNS: *

Importer Email: *

Importer Phone: *

Phone Extension:

CANCEL SAVE SAVE AND ADD

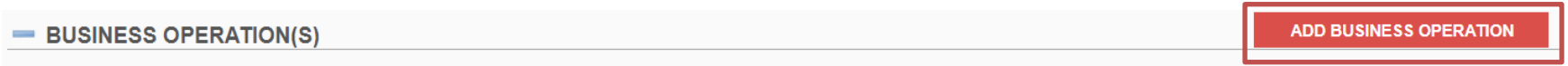
or more drug manufacturing and processing operations performed at the establishment.

ADD

Registering an Establishment

Step 11

Click on **Add Business Operation** to indicate the business operations taking place at the specific Establishment



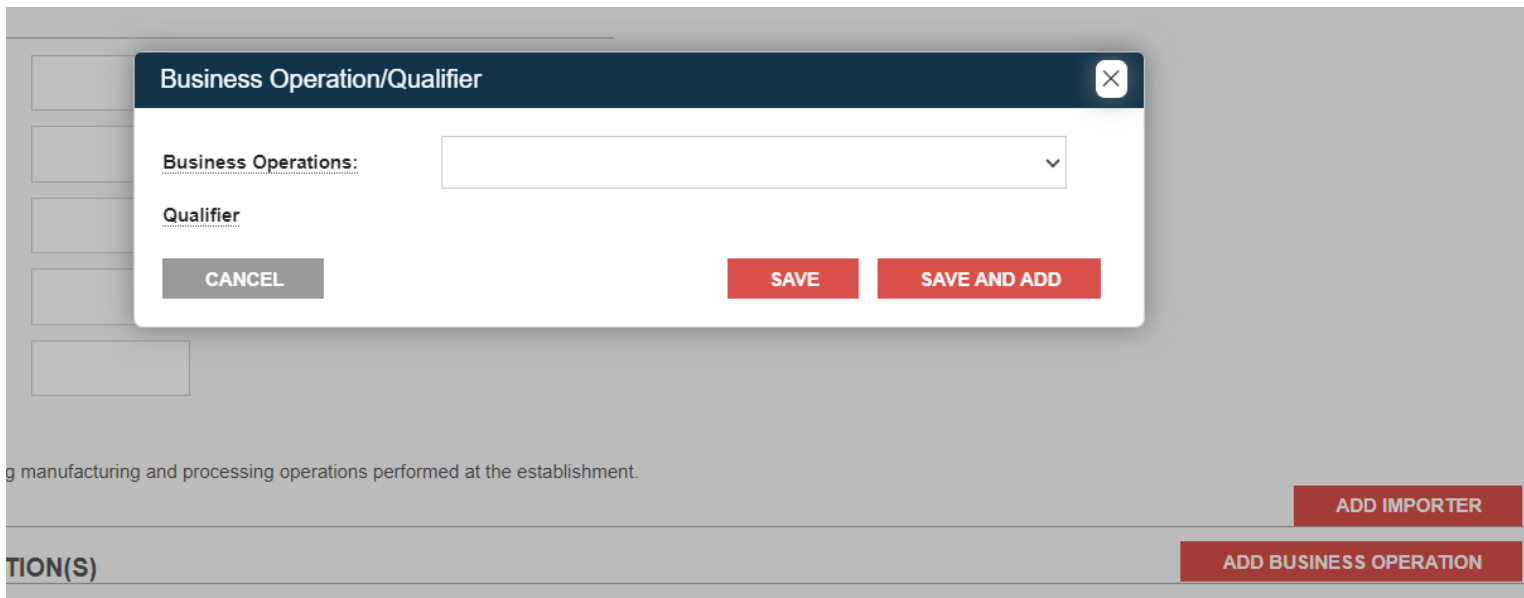
Step 12

Select the Business Operation(s) and associated Qualifier(s) performed at this establishment

Click **Save and Add** to quickly choose multiple business operations

Click **Save** once completed

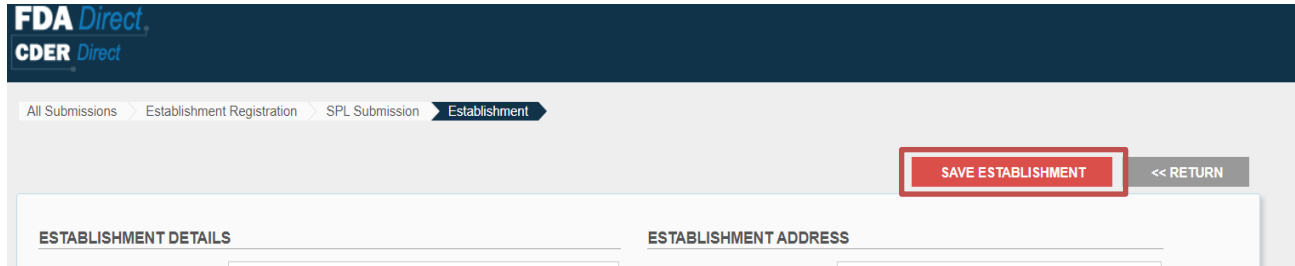
NOTE: Qualifier is required for all Business Operations except for Analysis, API Manufacture, and SIP Foreign Seller



Registering an Establishment

Step 13

Click on **Save Establishment**



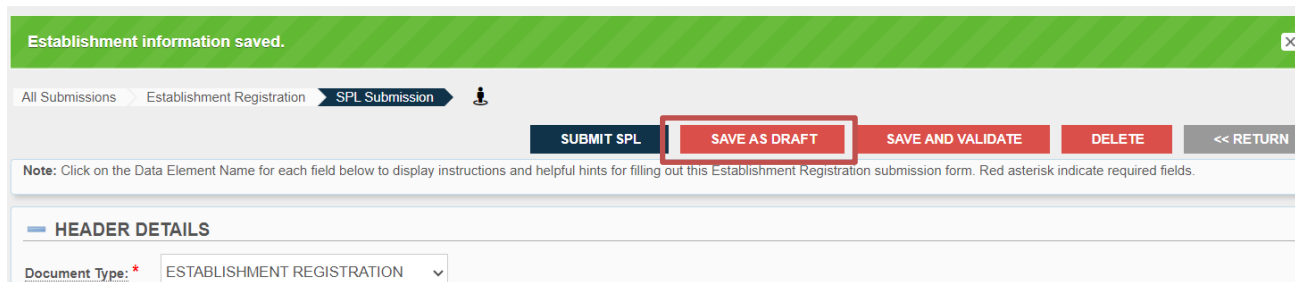
Step 14

If you have more establishments to register, click on **Add Establishment** and repeat steps 9-13



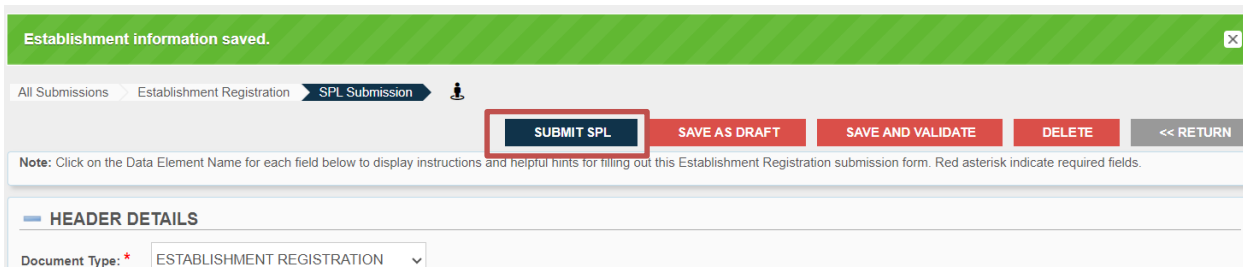
Step 15a

If there is still data to enter, click on **Save as Draft** to finish your submission later



Step 15b

If completed, click on **Submit SPL** to submit to FDA



Registering an Establishment

What happens after I click “Submit SPL”?

After clicking on Submit SPL, the submission undergoes an automated, technical validation indicated by the status of “Awaiting Acceptance”. This process takes approximately 15 minutes.

If the submission passes technical validation, the status will change to “Submission Accepted”.

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STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
AWAITING ACCEPTANCE	0bc8a2f0-7649-6f63-e063-fb95b40a2d26	0bc8a2f0-764a-6f63-e063-fb95b40a2d26		1	123456789	FDA Test	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
SUBMISSION ACCEPTED	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	e56fbe04-ae61-5383-e053-2a95af0a3d6c	cd6248173905.9325648017@direct	3	987654321	Wonder Pharma	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

Re-Registering or Updating an Establishment

Re-Registering or Updating an Establishment

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Password:

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OR

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Re-Registering or Updating an Establishment

Step 3

After logging in, click on **Establishment Registration** from the navigation pane on the left

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

ALL SUBMISSIONS

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SEARCH [] GO ACTIONS []

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	12-SEP-2023 13:43:08	
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	042a764f-be14-49a0-e063-6a94af0ae554		2	ESTABLISHMENT REGISTRATION	Regie Samuel	30-AUG-2023 16:09:51	
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

1 - 3

Step 4

Click on **Submission Accepted** for the most recently accepted Establishment Registration to renew

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
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 - 1

Re-Registering or Updating an Establishment

Step 5

Click on **Create New Version**, unlocking the SPL to review the SPL and make any updates

NOTE: After clicking **Create New Version**. The Header Details section will be automatically updated with the correct information

All Submissions > 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: * 835fa90e-d5b9-25c0-e053-2a91ab0abc1e

Root ID: * 835fa90e-d5ba-25c0-e053-2a91ab0abc1e

Version Number: * 1

Effective Date: * 05-01-2020

— REGISTRANT DETAILS

Registrant Name: * Wonder Pharma China

Step 6

Review the information in the SPL. Make any updates (ie contact information, business operations etc) if/as needed

After review and/or updates, click on **Submit SPL**

All Submissions > 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: * 953312a1-cac3-4ec8-e053-2995af0abd24 [Generate New](#)

Root ID: * 042a764f-be14-49a0-e063-6a94af0ae554 [Generate New](#)

Version Number: * 2

Effective Date: * 08-30-2023

Re-Registering or Updating an Establishment

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SUBMISSION ACCEPTED	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

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Re-Registering via No Change Notification*

**This option is only available October 1 – December 31*

Re-Registering via No Change Notification

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CDER Direct

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Re-Registering via No Change Notification

Step 3

Click on **Establishment Registration** from the navigation pane on the left

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration**
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

ALL SUBMISSIONS

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SEARCH [] GO ACTIONS []

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	12-SEP-2023 13:43:08	
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	042a764f-be14-49a0-e063-6a94af0ae554		2	ESTABLISHMENT REGISTRATION	Regie Samuel	30-AUG-2023 16:09:51	
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

1 - 3

Step 4

Click on **Submission Accepted** for the most recently accepted Establishment Registration to renew

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
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 - 1

Re-Registering via No Change Notification

Step 5

Click on **Create New Version**, unlocking the SPL to review the SPL and make any updates

NOTE: After clicking **Create New Version**, the Header Details section will be automatically updated with the correct information

All Submissions > 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: * 835fa90e-d5b9-25c0-e053-2a91ab0abc1e

Root ID: * 835fa90e-d5ba-25c0-e053-2a91ab0abc1e

Version Number: * 1

Effective Date: * 05-01-2020

REGISTRANT DETAILS

Registrant Name: * Wonder Pharma China

Step 6

Change **Document Type** to “No Change Notification”

NOTE: The option for “No Change Notification” is only available October 1 – December 31.

All Submissions > Establishment Registration > SPL Submission

PREVIEW SPL **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.

Note: If you have or are requesting an override for this SUBMISSION, DO NOT update any information and click on RETURN to go back to the DASHBOARD. Once overridden, the submission status will automatically get updated to SUBMISSION ACCEPTED

HEADER DETAILS

Document Type: * NO CHANGE NOTIFICATION

Set ID: * --Select One--

Root ID: * NO CHANGE NOTIFICATION

Version Number: * 2

Effective Date: * 12-20-2020

Step 7

Click on **Submit SPL**

Re-Registering via No Change Notification

What happens after I click "Submit SPL"?

After clicking on Submit SPL, the submission undergoes an automated, technical validation indicated by the status of "Awaiting Acceptance". This validation process takes approximately 15 minutes.

If the submission passes technical validation, the status will change to "Submission Accepted".

If the submission fails technical validation, the status will change to "Submission Failed". Click on **Submission Failed** to view and correct the errors identified. Then click on **Submit SPL** to resubmit.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
AWAITING ACCEPTANCE	0bc8a2f0-7649-6f63-e063-fb95b40a2d26	0bc8a2f0-764a-6f63-e063-fb95b40a2d26		1	123456789	FDA Test	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
SUBMISSION ACCEPTED	438cd80c-5447-4ac6-e054-00144ff8a759	438cd80c-5448-4ac6-e054-00144ff8a759	cd826731495.1860245973@direct	1	777777777	Core	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	e56fbe04-ae61-5383-e053-2a95af0a3d6c	cd6248173905.9325648017@direct	3	987654321	Wonder Pharma	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

De-Registering an Establishment

De-Registering an Establishment

Step 1 Navigate to FDA Direct by accessing: <https://direct.fda.gov>

Step 2 Enter your login credentials, accept the terms of service, and click **Login**

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links: [Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

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De-Registering an Establishment

Step 3

After logging in, click on **Establishment Registration** from the navigation pane on the left

All Submissions

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

NDC Labeler Code Request

Drug Listing and Certification

NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

Outsourcing Facility Registration

Compounded Drug Reporting

DSCSA ANNUAL REPORTING

Wholesale Drug Distributor and Third-Party Logistics Provider Reports

ALL SUBMISSIONS

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GO
ACTIONS ▾

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	12-SEP-2023 13:43:08	
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	042a764f-be14-49a0-e063-6a94af0ae554		2	ESTABLISHMENT REGISTRATION	Regie Samuel	30-AUG-2023 16:09:51	
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

1 - 3

Step 4

Click on **Submission Accepted** for the most recently accepted Establishment Registration containing the Establishment(s) to de-register

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
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 - 1

Step 5

Click on **Create New Version**, unlocking the SPL to review the SPL and make any updates

All Submissions > 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

<u>Document Type:</u> *	ESTABLISHMENT REGISTRATION		
<u>Set ID:</u> *	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	<u>Version Number:</u> *	1
<u>Root ID:</u> *	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	<u>Effective Date:</u> *	05-01-2020

— REGISTRANT DETAILS

<u>Registrant Name:</u> *	Wonder Pharma China
---------------------------	---------------------

De-Registering an Establishment

Step 6a

To de-register ALL Establishments in this registration, change the Document Type to **Establishment De-Registration**

To indicate that the Establishment(s) is(are) out of business, select **Out of Business Notification**

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 ▾

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

Version Number: *

Effective Date: *

Set ID: * [Generate New](#)

Root ID: * [Generate New](#)

Step 6b

To de-register less than all the Establishments in this registration, simply click on the edit tool next to the Establishment(s) to de-register and click on **Delete Establishment**

Ensure only the Establishment(s) you want registered are still in the SPL

ADD ESTABLISHMENT

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	987654321	1234567	Wonder Pharma

SAVE ESTABLISHMENT
DELETE ESTABLISHMENT
<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI: *

ESTABLISHMENT ADDRESS

Country: * ▾

Street Address: *

City: *

Step 7

Click on **Submit SPL**

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

<u>Document Type:</u> *	<input type="text" value="ESTABLISHMENT DE-REGISTRATION"/>		
<u>Set ID:</u> *	<input type="text" value="953312a1-cac3-4ec8-e053-2995af0abd24"/>	Generate New	<u>Version Number:</u> * <input type="text" value="2"/>
<u>Root ID:</u> *	<input type="text" value="cd28a52e-c5c7-bf7e-e053-2995af0adb9a"/>	Generate New	<u>Effective Date:</u> * <input type="text" value="09-28-2023"/>

De-Registering an Establishment

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STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER
AWAITING ACCEPTANCE	0bc8a2f0-7649-6f63-e063-fb95b40a2d26	0bc8a2f0-764a-6f63-e063-fb95b40a2d26		1	123456789	FDA Test	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

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Uploading an Establishment Registration SPL File

Uploading an Establishment Registration SPL File

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FDA Direct
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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Uploading an Establishment Registration SPL File

Step 3

After logging in, click on **Establishment Registration** from the navigation pane on the left

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

ALL SUBMISSIONS

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SEARCH [] GO ACTIONS []

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION FAILED	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	12-SEP-2023 13:43:08	
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	042a764f-be14-49a0-e063-6a94af0ae554		2	ESTABLISHMENT REGISTRATION	Regie Samuel	30-AUG-2023 16:09:51	
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	01-OCT-2018 11:55:10	

1 - 3

Step 4

Click on **Create New/Upload File**

SEARCH [] 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
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a		2	987654321	Wonder Pharma	ESTABLISHMENT DE-REGISTRATION	DETAILS	Regie Samuel	14-DEC-2023 11:53:23
SUBMISSION	835fa90e-d5b9-25c0-	835fa90e-d5ba-25c0-				Wonder Pharma	ESTABLISHMENT	DETAILS	Regie	01-OCT-2018

Uploading an Establishment Registration SPL File

Step 5

Click on **Import an existing Establishment Registration SPL** and then Continue

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

Step 6

Click on **Establishment Registration File**

Locate and select the Establishment Registration ZIP file to upload into CDER Direct and click **Upload**

UPLOAD ESTABLISHMENT REGISTRATION FILE

Establishment Registration File 

Select a file or drop one here.

Note: Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that are referenced in the xml whose names end in '.jpg'.

UPLOAD CANCEL

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