

# Reference Guide: Human Drug Product Listing

## Welcome to Human Drug Product Listing in the FDA Direct Portal

This guide provides the essential information you need to list a human drug product or upload a drug product listing SPL file into FDA Direct.

For technical support, email the eDRLS Help Desk at [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov).

**FDA Direct**  
CDER Direct & Cosmetics Direct

### 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](#)

### 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

Listing a Human Drug Product	<a href="#"><u>3</u></a>
Uploading Drug Product Listing SPL File	<a href="#"><u>21</u></a>
Assistance with Errors	<a href="#"><u>25</u></a>

## **Listing a Human Drug Product**

# Listing a Human Drug Product

**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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# Listing a Human Drug Product

## Step 3

Click on **Drug Listing and Certification**

## Step 4

Click on **Create New/Upload File**

# Listing a Human Drug Product

## Step 5

Click on **Create a New Drug Listing and Certification using a blank form** and **Select the appropriate SPL Document Type** for the drug product you want to list. Then click **Continue**

**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

**CREATE NEW DRUG LISTING AND CERTIFICATION**

Create a New Drug Listing and Certification using a blank form

Import an existing Drug Listing and Certification SPL

**SPL Document Type:** \* -- Select Document Type --

**Note:** To update an existing submission, click [ID] from the table in the prior page / Dashboard.

**CONTINUE** **CANCEL**

- Select Document Type --
- BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
- BULK INGREDIENT
- CELLULAR THERAPY
- DRUG FOR FURTHER PROCESSING
- HUMAN OTC DRUG LABEL**
- HUMAN PRESCRIPTION DRUG LABEL
- LICENSE BLOOD INTERMEDIATES/PASTE LABEL
- LICENSED MINIMALLY MANIPULATED CELLS LABEL
- LICENSED VACCINE BULK INTERMEDIATE LABEL
- NON-STANDARDIZED ALLERGENIC LABEL
- PLASMA DERIVATIVE
- STANDARDIZED ALLERGENIC
- VACCINE LABEL

## Step 6

The 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 by FDA is considered the date it is effective.

All Submissions > Drug Listing and Certification > **Products**

**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 Products submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

**Document Type:** \* HUMAN OTC DRUG LABEL

**Version Number:** \* 1

**Set ID:** \* 1365f68a-c52a-64b2-e063-6a94af0a9586 [Generate New](#)

**Effective Date:** \* 03-11-2024

**Root ID:** \* 1365f68a-c52b-64b2-e063-6a94af0a9586 [Generate New](#)

**Title**

# Listing a Human Drug Product

## Step 7

### Enter the Labeler Details.

This Labeler Name and Labeler DUNS is the information associated with the Labeler Code for which the drug listing is being completed.

### 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

**LABELER DETAILS**

Labeler Name: \*  Labeler DUNS: \*

**REGISTRANT DETAILS**

Registrant Name:  Registrant DUNS:

Confidential

**LABELER DETAILS**

Labeler Name: \*  Labeler DUNS: \*

**REGISTRANT DETAILS**

Registrant Name:

Confidential

**Registrant Name** ✕

The registrant is the owner or operator of the establishment manufacturing a drug. If listing for a private label distributor, include this information otherwise leave this part blank.

NOTE: Registrant Name and Registrant DUNS does not refer to the firm submitting the listing.

# Listing a Human Drug Product

## Step 8

Click on **Add Establishment**

ESTABLISHMENTS  
None

ADD ESTABLISHMENT

## Step 9

**Enter the Establishment Details** for the Establishment performing a business operation on the drug product.

**Select the Business Operation** being performed on the **Product NDC** being listed. Click the + to add multiple business operations or Product NDCs.

**Click on Save Establishment.**

Repeat Steps 8 and 9 for additional establishments

SAVE ESTABLISHMENT    DELETE ESTABLISHMENT    << RETURN

**ESTABLISHMENT DETAILS**

Establishment Name: \*       Establishment DUNS: \*

Confidential

**BUSINESS OPERATION(S)** ⓘ

+	BUSINESS OPERATION	PRODUCT NDC
✖	--Select One-- --Select One-- ANALYSIS API MANUFACTURE API/FDF ANALYTICAL TESTING CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY FDF MANUFACTURE IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING LABEL MANUFACTURE MEDICATED ANIMAL FEED MANUFACTURE PACK PARTICLE SIZE REDUCTION POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION RELABEL REPACK STERILIZE	<input type="text"/>

\*Enter the first two segments of NDC (Labeler Code-Product Code) being listed

\*Business operation selected here must match a business operation that exists in this Establishment's Establishment Registration SPL



# Listing a Human Drug Product

## Step 10

Click on Add Product

## Step 11

Enter the information regarding the drug product being listed.

The first segment of the Product NDC should be the Labeler Code associated with the Labeler DUNS from Step 7.

Click on the fieldname with the dotted underline for a description of what should be entered in each field.

# Listing a Human Drug Product

## Step 12

Enter the Marketing Details for the Product.

**Marketing Start Date** should correspond to the date that the product enters commercial distribution in the United States.

**MARKETING DETAILS**

Marketing Status: \*

Marketing Start Date: \*

Marketing Category: \*

Application Number/  
Monograph ID:

## Step 13

Click on Add Ingredient

**INGREDIENTS**

None

[ADD INGREDIENT](#)

# Listing a Human Drug Product

## Step 14a

Select the appropriate “Type” and enter the information regarding the Active Ingredient(s) individually and Save Ingredient.

\*The strength of the active ingredient should be expressed as a fraction (numerator/denominator).

SAVE INGREDIENT
<< RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

---

**INGREDIENT DETAILS**

Type: \* -- Select One --

Ingredient UNII - Name: \* -- Select One --

Numerator Strength: \*

Denominator Strength: \*

Unit of Measure: \* -- Select One --

-- Select One --

Active Ingredient, Ingredient is Basis of Strength

Active Ingredient, Moiety is Basis of Strength

Active Ingredient, Reference Ingredient is Basis of Strength

Inactive Ingredient

## Step 14b

After clicking on Save Ingredient, click on Add Ingredient to add additional ingredients such as Inactive Ingredients.

Inactive Ingredients can be marked Confidential to prevent information from being released to public repositories.

SAVE INGREDIENT
<< RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

---

**INGREDIENT DETAILS**

Type: \* Inactive Ingredient

Ingredient UNII - Name: \*

Confidential:

Numerator Strength:

Denominator Strength:

Unit Of Measure: -- Select One --

Unit of Measure: -- Select One --

# Listing a Human Drug Product

## Step 15

If the product is in a solid oral dosage form (i.e. tablet), click on Choose File, locate and select a JPG image of the product (i.e. tablet) and click Open.

Once the file path is visible in the gray box, click Upload Image.

PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY) UPLOAD IMAGE

**Important:** Do not enter package images and other labeling. These should be uploaded under the Content of Labeling tab.

Select a File:  Choose File

## Step 16

If the product is in a solid oral dosage form, Click on Add Characteristic to add characteristics as needed.

Click on Save Characteristic and repeat this step for each characteristic.

Color, Shape, Size, and Score are required for solid oral dosage forms.

CHARACTERISTICS ADD CHARACTERISTIC

None

SAVE CHARACTERISTIC << RETURN

CHARACTERISTICS

Characteristic: \*

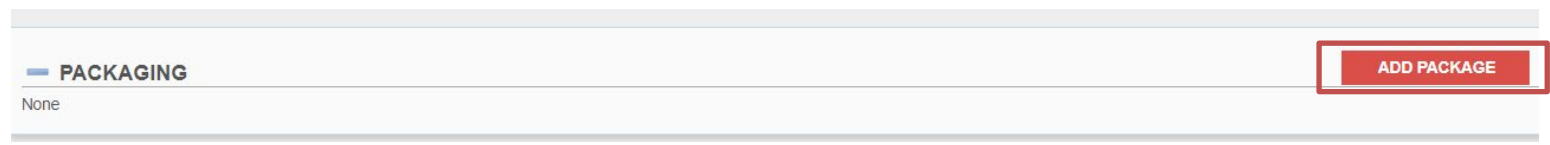
Value: \*

- Color
- Flavor
- Imprint
- Score
- Shape
- Size (mm)

# Listing a Human Drug Product

## Step 17

To add Package details, click on Add Package.



## Step 18

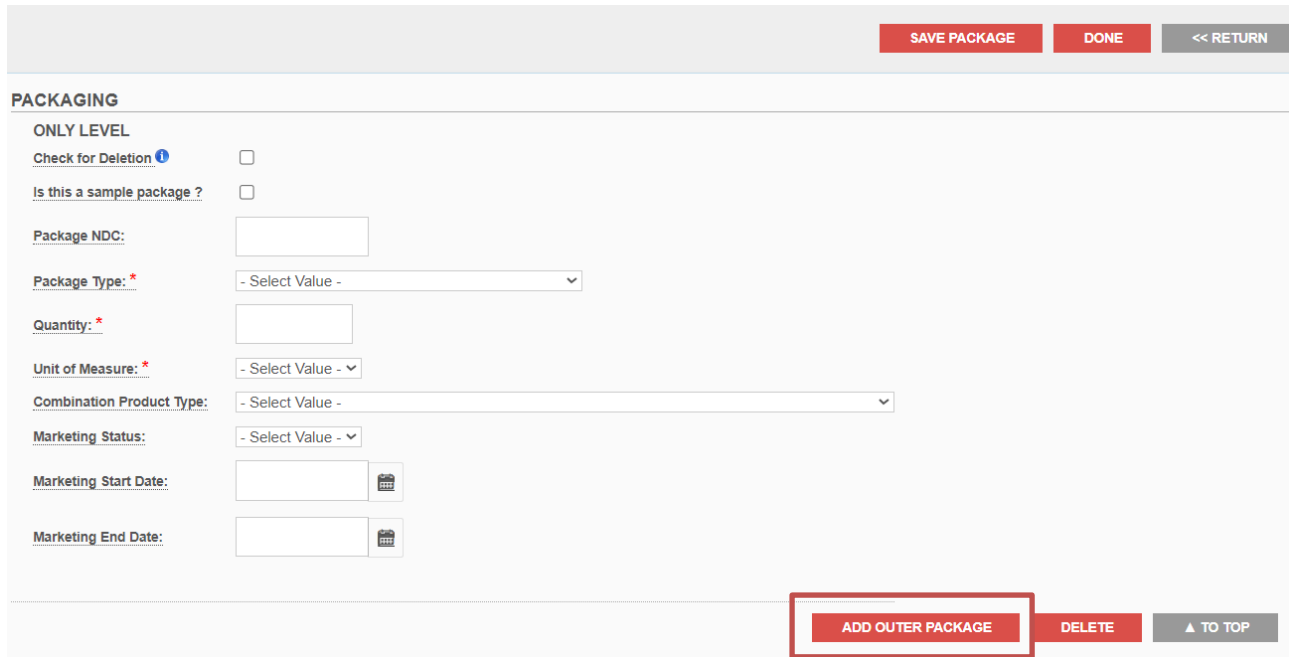
Enter the Package information.

Click on “Add Outer Package” for additional levels of packaging (ie bottle within a carton).

Click on Save Package

## Step 19

Repeat steps 17 and 18 to add additional package presentations associated with the product



# Listing a Human Drug Product

## Step 20

After completing the fields for the Product Data Elements, click on Save Product

**PRODUCT DATA ELEMENTS**

NDC Product Code: \*

Proprietary Name: \*

Non Proprietary Name: \*

Suffix:

DEA Schedule: -- Select DEA Schedule -- ▾

SAVE PRODUCT | DELETE PRODUCT | << RETURN

## Step 21

To add another product, click on “Add Product” and repeat steps 11-20.

\*Please note that multiple Product NDCs can only be listed in the same Product Listing SPL if the Product NDCs share the same Content of Label. Otherwise, you must create a new, different Product Listing SPL.

PRODUCTS | ADD PRODUCT

Q ▾ GO ACTIONS ▾

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	CLONE PRODUCT
	00000-000	-	-	

# Listing a Human Drug Product

## Step 20

To add Content of Labeling information, click on Content of Labeling.

## Step 21

To add a Section, click on Add Section

## Step 22

Select the Section Type from the drop-down menu and enter Effective Date.

Enter the information for the Section in the “Content” editor.

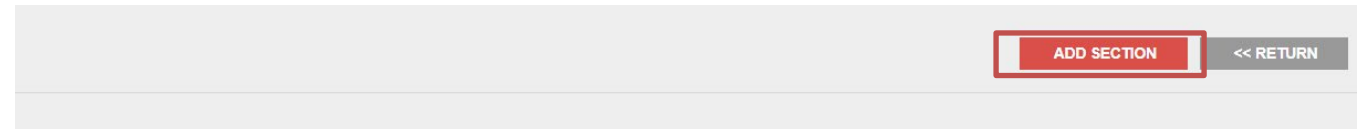
Once finished with a section, click on “Save Section”

# Listing a Human Drug Product

## Step 23

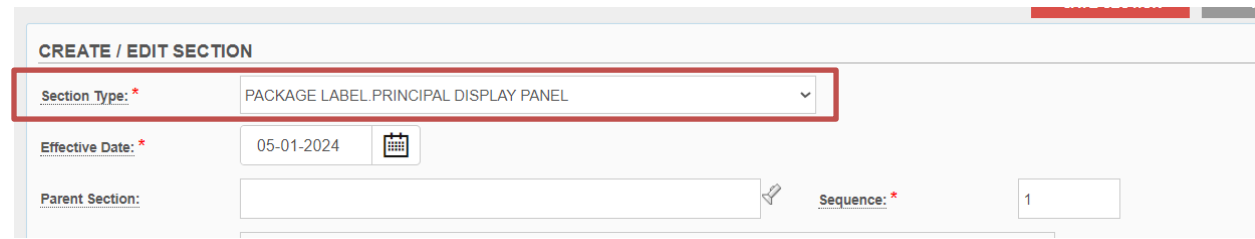
To add multiple sections, repeat steps 21 and 22.

To add an image of the Package Label, click on Add Section



## Step 24

For Section Type, select Package Label Principal Display Panel

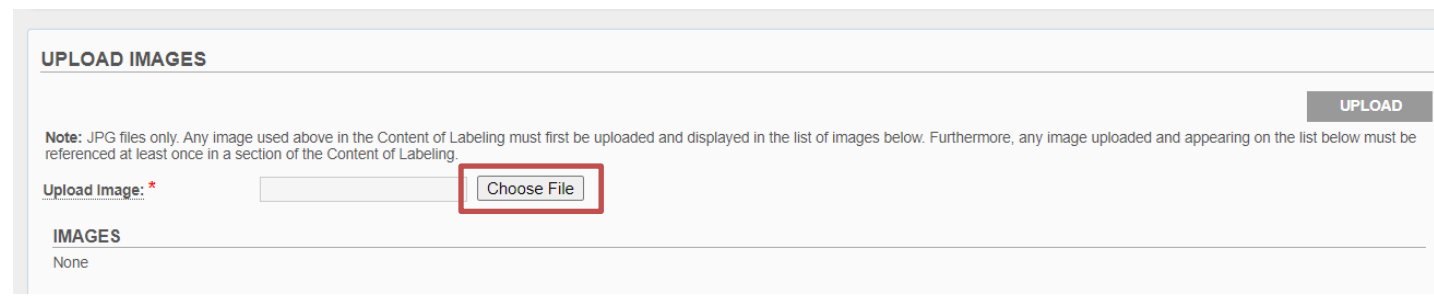


## Step 25

Click on "Choose File" to select the package label image you want to upload.

Locate and select the image file you want to upload.

\*Only .jpg or .jpeg files less than 1MB are accepted





# Listing a Human Drug Product

## Step 26

The file path will populate to the left of “Choose File”.  
Click on Upload.

**UPLOAD IMAGES**

**UPLOAD**

Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.

Upload Image: \*

**IMAGES**

None

## Step 27

If successful, the image will appear under “Images”.


**UPLOAD IMAGES**

**UPLOAD**

Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.

Upload Image: \*

**IMAGES**

IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED
<a href="#">images.jpg</a>		✘	No

1 - 1

## Step 28

To add the image into the Content box, click on the “Insert an image” icon (sunset with green plus sign)

**Content:**

Rich text editor toolbar with icons for Bold, Italic, Underline, Bulleted List, Numbered List, Undo, Redo, Link, **Insert Image** (sunset with green plus sign), Table, Link, Unlink, Source.

# Listing a Human Drug Product

## Step 29

Select the Image you want to add, enter Image Text and click OK

**Image Properties** ✕

Image Name\*  
 ▾

Image Text\*

Note: To insert an image not in the above list, first upload an image by clicking the "Upload" button in the underlying screen. The image will then appear in this list.



## Step 30


The image should now appear in the Content box.

To add another Package Label image, repeat steps 25-29

When the section is complete, click Save Section

Content:

B I U x<sub>2</sub> x<sup>2</sup> I<sub>x</sub>
☰ ☱
✂ 📄 📁 📁 📁
↶ ↷
🔗
🗃 🌐 a<sup>1</sup>
📄 Source



# Listing a Human Drug Product

## Step 29

Once all sections have been added, click on Return

## Step 30

To Preview SPL, click on "Preview SPL"

To Submit SPL to FDA, click on Submit SPL

To save work and return for completion at a different time, click Save as Draft

To check for validation errors prior to submitting to FDA, click on Save and Validate

All Submissions > Drug Listing and Certification > Products

CONTENT OF LABELING | PREVIEW SPL | 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 Products submission form. Red asterisk indicate required fields.

**— HEADER DETAILS**

<b>Document Type:</b> *	HUMAN OTC DRUG LABEL	<b>Version Number:</b> *	1
<b>Set ID:</b> *	17677fc1-7a8e-916d-e063-6394a90a268c <a href="#">Generate New</a>	<b>Effective Date:</b> *	05-01-2024
<b>Root ID:</b> *	17677fc1-7a8f-916d-e063-6394a90a268c <a href="#">Generate New</a>		

# Listing a Human Drug Product

## 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”.

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
<a href="#">AWAITING ACCEPTANCE</a>	0bc8a2f0-7649-6f63-e063-fb95b40a2d26	0bc8a2f0-764a-6f63-e063-fb95b40a2d26		1	123456789	FDA Test	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>	John Johnson

## Uploading a Drug Product Listing SPL File

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# Uploading a Drug Product Listing SPL File

## Step 3

After logging in, click on **Drug Listing and Certification** 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**

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

Q v GO ACTIONS v

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">SUBMISSION FAILED</a>	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regie Samuel	12-SEP-2023 13:43:08	
<a href="#">DRAFT</a>	953312a1-cac3-4ec8-e053-2995af0abd24	042a764f-be14-49a0-e063-8a94af0ae554		2	ESTABLISHMENT REGISTRATION	Regie Samuel	30-AUG-2023 16:09:51	
<a href="#">SUBMISSION ACCEPTED</a>	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**

**DRUG LISTING AND CERTIFICATION**

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- Product listing that is newly listed or updated during the current calendar year is certified through December 31 of the following calendar year.
- Blanket No Changes Certification SPL can only be submitted from October 1 – December 31.
- Only a status of "Submission Accepted" indicates that a submission has successfully passed automated validation and been received by FDA.
- Products will appear on the [National Drug Code \(NDC\) Directory](#) only after the marketing start date has been reached. Please note that not all products are published on the NDC Directory as noted under "[Important Considerations about the NDC Directory](#)".

Q v GO ACTIONS v SEARCH PRODUCT **CREATE NEW / UPLOAD FILE**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">DRAFT</a>	17677fc1-7a8e-916d-e063-6394a90a268c	17677fc1-7a8f-916d-e063-6394a90a268c		1	HUMAN OTC DRUG LABEL	-	<a href="#">DETAILS</a>	Regie Samuel	01-MAY-2024 15:55:41	

# Uploading a Drug Product Listing SPL File

## Step 5

Click on **Import an existing Drug Listing and Certification SPL** and then Continue

**CREATE NEW DRUG LISTING AND CERTIFICATION**

Create a New Drug Listing and Certification using a blank form

**Import an existing Drug Listing and Certification 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 **Drug Listing and Certification File**

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

**UPLOAD DRUG LISTING AND CERTIFICATION FILE**

**Drug Listing and Certification 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**



For assistance with errors received in CDER Direct, contact **[CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov)**.