

Reference Guide: Blanket No Changes Certification of Product Listing

FDA

Welcome to Blanket No Changes Certification of Product Listing in the FDA Direct Portal

This guide provides the essential information on the requirements for certifying drug listings using the Blanket No Changes Certification SPL, applicable only for no changes between October 1 and December 31.

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

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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Blanket No Changes Certification of Product Listing

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FDA

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

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

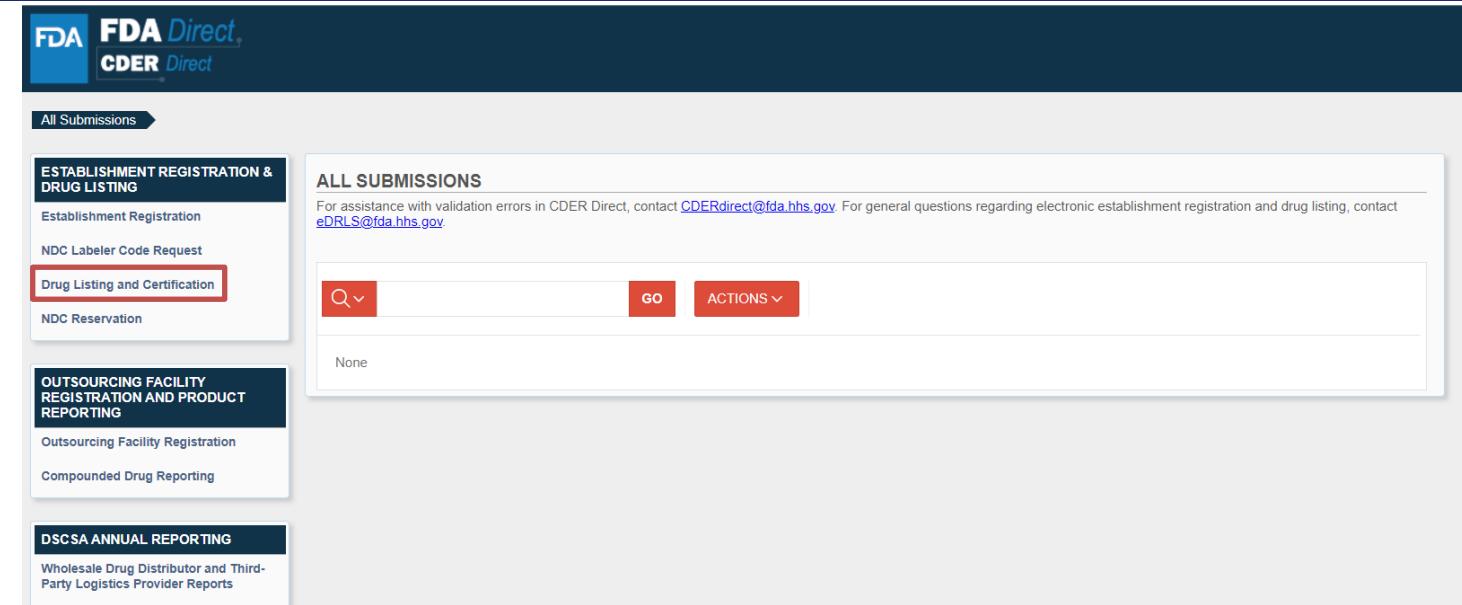
Blanket No Changes Certification of Product Listing

Step 3

Click on **Drug Listing and Certification**

Note:

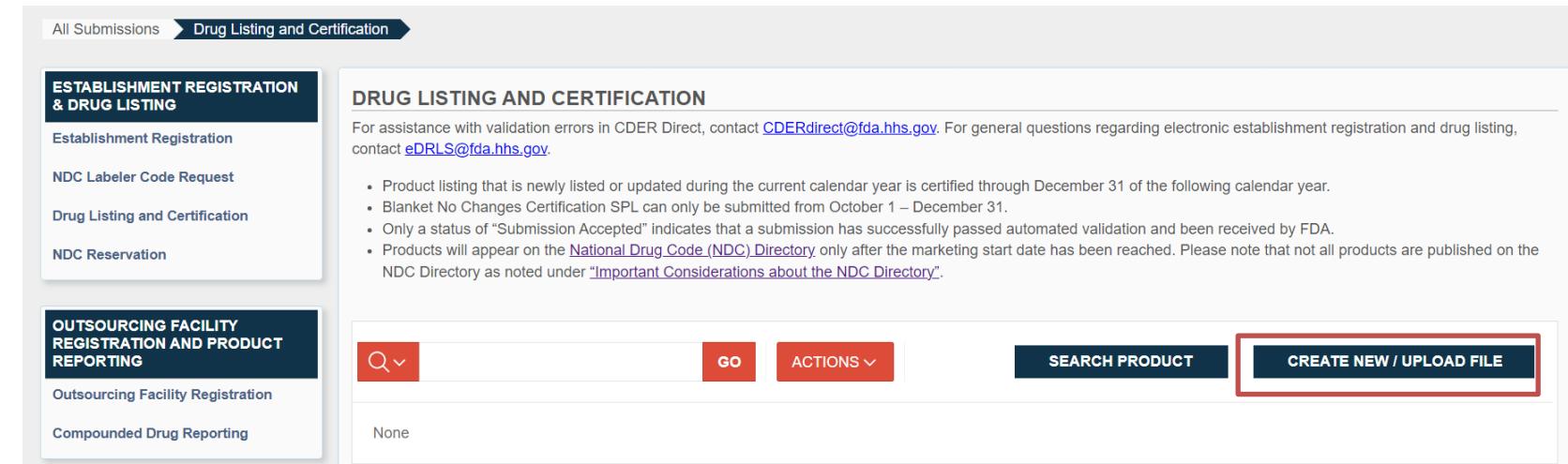
The Blanket No Changes Certification does not affect Establishment Registration files and cannot be used for establishment registration or to annually renew an establishment registration.



The screenshot shows the 'All Submissions' section of the FDA Direct CDER Direct interface. On the left, there are three main categories: 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. Under 'ESTABLISHMENT REGISTRATION & DRUG LISTING', the 'Drug Listing and Certification' option is highlighted with a red box. The right side of the screen shows the 'ALL SUBMISSIONS' list, which is currently empty, indicated by the text 'None'.

Step 4

Click on **Create New/Upload File**



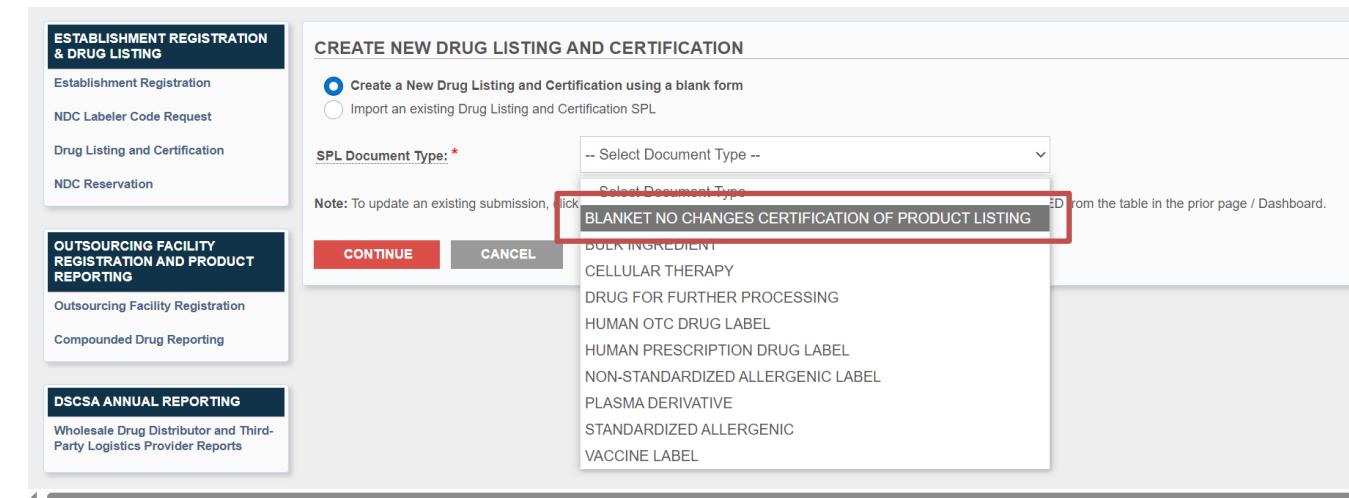
The screenshot shows the 'Drug Listing and Certification' page. On the left, there is a sidebar with links to 'Establishment Registration', 'NDC Labeler Code Request', 'Drug Listing and Certification' (which is the current page), and 'NDC Reservation'. On the right, there is a 'DRUG LISTING AND CERTIFICATION' section with instructions and a bulleted list of requirements. Below this is a search bar and a 'CREATE NEW / UPLOAD FILE' button, which is highlighted with a red box.

Blanket No Changes Certification of Product Listing

Step 5

Click on **Create a New Drug Listing and Certification** using a blank form and **Select Blanket No Changes Certification of Product Listing** and select **Continue**

Note: Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.



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: *

CONTINUE CANCEL

Note: To update an existing submission, click [Edit](#) from the table in the prior page / Dashboard.

-- Select Document Type --

Select Document Type

BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING

CONTINUE CANCEL

DIRECT INGREDIENT
CELLULAR THERAPY
DRUG FOR FURTHER PROCESSING
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG 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: Because this is a single submission every year, you can use the auto generated SET ID and Root ID.

HEADER DETAILS

Document Type: *	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING		
Set ID: *	21b3f762-c85b-7b2c-e063-fa95b40adb08	Generate New	Version Number: *
Root ID: *	21b3f762-c85c-7b2c-e063-fa95b40adb08	Generate New	Effective Date: *
			09-09-2024 

Blanket No Changes Certification of Product Listing

Step 7

Enter the Authorized Agent Details. Authorized Agent is generally the same as CDER Direct account owner

AUTHORIZED AGENT DETAILS

Same as CDER Direct account details.

Organization DUNS: *

Organization Name: *

Phone Number: * [Format](#)

Name: *

Email: *

Phone Extension:

SEARCH

Step 8

Click on “Add Labeler” button and enter the labeler code of the product(s) you wish to certify.

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

ADD LABELER

Use drug listing files are certified for.

Refresh Establishments button to update the establishment list based on the labeler selection.

Check in the report header for "Select All" functionality.

ADD LABELER CODE

LABELER CODE:

ADD

REFRESH ESTABLISHMENTS

HOW PRODUCTS **ADD ESTABLISHMENT**

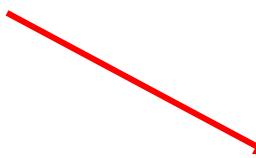
GO Rows 15 **ACTIONS**

Blanket No Changes Certification of Product Listing

Step 8

“Refresh Establishments” to find all the establishments that are involved with the Labeler(s). products.

Select the **checkbox** to choose all the establishments or just choose specific establishments



	LABELER CODE	NAME	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	55555	Wonderpharma	John Doe, 918-282-2827, Wonderpharma@Wonderpharma.com	

1 - 1

REFRESH ESTABLISHMENTS

ESTABLISHMENTS		SHOW PRODUCTS	ADD ESTABLISHMENT
----------------	--	---------------	-------------------

Note:* Establishments whose drug listing files are certified for.

* The list below only contains those establishments associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been previously indicated as confidential, please use the Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

* Use check box in the report header for "Select All" functionality.

	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	987654321	Wonder Pharma	123 Main St, Some City, VA, 20171, USA	Wonder Pharma, 927-187-9878, wonderpharma@wonderpharma.com	

1 - 1 of 1

ESTABLISHMENTS		SHOW PRODUCTS
----------------	--	---------------

Note:* Establishments whose drug listing files are certified for.

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* Use check box in the report header for "Select All" functionality.

ADD ESTABLISHMENT DUNS

ESTABLISHMENT DUNS:

111110000

ADD

	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS
<input checked="" type="checkbox"/>	987654321	Wonder Pharma	123 Main St, Some City, VA, 20171, USA	Wonder Pharma, 927-187-9878, wonderpharma@wonderpharma.com

Step 9

To add establishments that may have been previously indicated as confidential, please use the “Add Establishment” button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

Blanket No Changes Certification of Product Listing

Step 10

Once you have your establishments marked you should select “**Show Products**”. This will result in a list of products where you can choose to certify all or any of the products

ESTABLISHMENTS

SHOW PRODUCTS **ADD ESTABLISHMENT**

Note:* Establishments whose drug listing files are certified for.

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	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	987654321	Wonder Pharma	123 Main St, Some City, VA, 20171, USA	Wonder Pharma, 927-187-9878, wonderpharma@wonderpharma.com	

1 - 1 of 1

PRODUCTS INCLUDED IN SUBMISSION

PRODUCT NDC	PROPRIETARY NAME
55555-111	WonderPatch
55555-222	WonderGel
55555-777	Wonderdrug
55555-999	Wondercream

row(s) 1 - 4 of 4

**Step 11**

Select the checkbox to choose the products you wish to certify. You can select all the products by checking the top



Q	GO	Rows 15	ACTIONS					
	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	dosage form name	ACTIVE INGREDIENTS	STATUS	DELETE
<input checked="" type="checkbox"/>	55555-111	WonderPatch	-	26-MAR-23	PATCH	SALICYLIC ACID (40 1+)	Uncertified	
<input checked="" type="checkbox"/>	55555-222	WonderGel	-	26-MAR-23	GEL	SALICYLIC ACID (40 1+)	Uncertified	
-	55555-333	Wonderdrug	-	26-MAR-23	TABLET	COAL TAR (200 mg)	Inactivated	-
<input checked="" type="checkbox"/>	55555-777	Wonderdrug	-	26-MAR-23	TABLET	COAL TAR (2000 mg)	Uncertified	
<input checked="" type="checkbox"/>	55555-999	Wondercream	-	26-MAR-23	CREAM	COAL TAR (5 g/100 g)+	Uncertified	

1 - 5 of 5

Step 12: After you have selected the products you wish to certify select "SAVE/UPDATE"

Note: If you don't find your Product NDC in the list, you can add it using the "Add Prod NDC"

Blanket No Changes Certification of Product Listing

Drug Listing Certification Status Definitions

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.

Uncertified: This product listing has not been certified for the next calendar year and is available for certification.

Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.

Completed: Product is discontinued. The listing data is not available for certification.

Current: The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.

Validation Errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.

Inactivated: The listing data for this product has been inactivated by FDA and cannot be certified.

Expired: The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data

ACTIVE INGREDIENTS	STATUS	DELETE
SALICYLIC ACID (40 1+)	Uncertified	X
SALICYLIC ACID (40 1+)	Uncertified	X
COAL TAR (200 mg)	Inactivated	-
COAL TAR (2000 mg)	Uncertified	X
COAL TAR (5 g/100 g)+	Uncertified	X

1 - 5 of 5

Step 13

Submit SPL

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 Certification submission form. Red asterisk indicate required fields.

* Please note that the Blanket No Changes Certification of Product Listing is intended to certify [Drug Listing files only](#). The Blanket No Changes Certification [does not affect Establishment Registration files](#) and cannot be used for establishment registration or to annually renew an establishment registration.

* To submit an annual Establishment Registration, use the document type Establishment Registration or No Change Notification.

HEADER DETAILS

Document Type: * BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING

Set ID: * 20c1c8d9-ef9b-081c-e063-6a94af0ad7e9 [Generate New](#)

Version Number: * 2

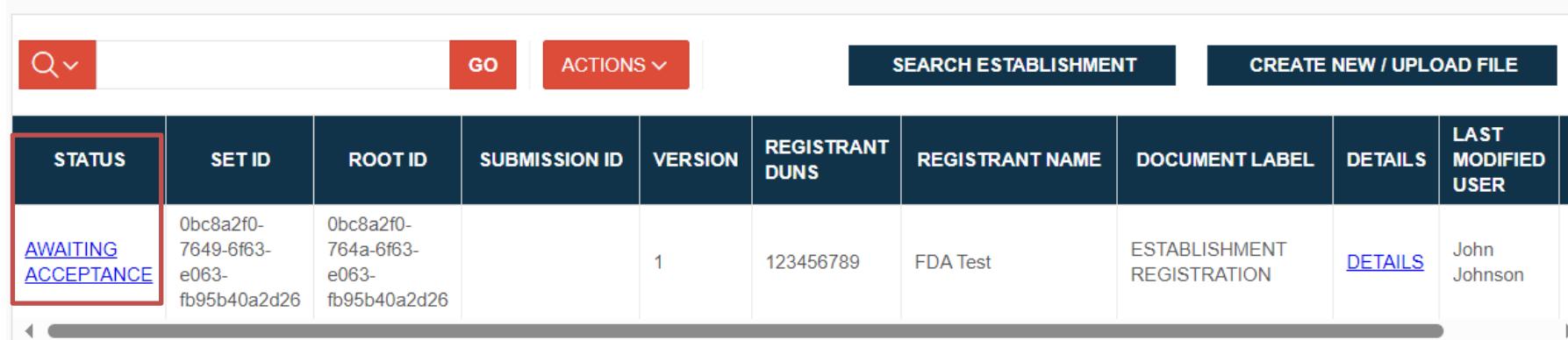
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What happens after I click “Submit SPL”?

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.



Q ▾	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
AWAITING ACCEPTANCE	0bc8a2f0-7649-6f63-e063-fb95b40a2d26	0bc8a2f0-764a-6f63-e063-fb95b40a2d26		1	123456789	FDA Test	ESTABLISHMENT REGISTRATION	DETAILS	John Johnson

Uploading a Product Listing SPL File

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Uploading a Product Listing SPL File

Step 3

After logging in, click on **Drug Listing and Certification** from the navigation pane on the left

Note:

If you choose to update a blanket no changes certification with the same SET ID, remember to include all NDCs from the previous version or else they will be replaced by the new version.

Step 4

Click on **Create New/Upload File**

Uploading a 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 on **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.**