


# Reference Guide: Blanket No Changes Certification of Product Listing

## 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](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


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## **Blanket No Changes Certification of Product Listing**

# Blanket No Changes Certification of Product Listing

**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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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 no later than 1 year after the date of enactment. In addition to the registration requirements, 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 your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCC) about cosmetic manufacturers and products in the marketplace.

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/>.

### 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.

FDA

FDA Direct  
CDER Direct

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

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

GO

ACTIONS

None

### Step 4

Click on **Create New/Upload File**

All Submissions

Drug Listing and Certification

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

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

GO

ACTIONS

SEARCH PRODUCT

CREATE NEW / UPLOAD FILE

None

## 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: \*

-- Select Document Type --

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

NON-STANDARDIZED ALLERGENIC LABEL

PLASMA DERIVATIVE

STANDARDIZED ALLERGENIC

VACCINE LABEL

Note: To update an existing submission, click

ED from the table in the prior page / Dashboard.

CONTINUE

CANCEL

## 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](#)

Root ID: \*

21b3f762-c85c-7b2c-e063-fa95b40adb08

[Generate New](#)

Version Number: \*

1

Effective Date: \*

09-09-2024

## 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: \*

Name: \*

Email: \*

Phone Extension:

[Format](#)

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

se drug listing files are certified for.

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

ix in the report header for "Select A

ADD LABELER CODE

LABELER CODE:

ADD

REFRESH ESTABLISHMENTS

SHOW PRODUCTS

ADD ESTABLISHMENT

ENTS

its whose drug listing files are cert

y only contains those establishments

icated as confidential, please use the Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be

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

GO

Rows

15

ACTIONS

### 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

### 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.

<input type="checkbox"/>	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.

Q

GO

Rows 15

ACTIONS

<input type="checkbox"/>	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 cert

\* The list below only contains those establishme

previously indicated as confidential, please use

included.

\* Use check box in the report header for "Select A

Q

GO

Rows 15

ACTIONS

ADD ESTABLISHMENT DUNS

ESTABLISHMENT DUNS: 11111000d

ADD

<input type="checkbox"/>	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@wonder



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.

\* 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.

Q

GO

Rows 15

ACTIONS

	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

SAVE / UPDATE

ADD PROD NDC

RETURN

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 type="checkbox"/>								
<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	✕
<input type="checkbox"/>	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"

## 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	✕
SALICYLIC ACID (40 1+)	Uncertified	✕
COAL TAR (200 mg)	Inactivated	-
COAL TAR (2000 mg)	Uncertified	✕
COAL TAR (5 g/100 g)+	Uncertified	✕

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

### 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.


<div><div>Q</div><div></div><div>GO</div><div>ACTIONS</div><div>SEARCH ESTABLISHMENT</div><div>CREATE NEW / UPLOAD FILE</div></div>									
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 Product Listing SPL File

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### 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.

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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Q v

GO

ACTIONS v

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**

DRUG LISTING AND CERTIFICATION

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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	
DRAFT	17677fc1-7a8e-916d-e063-6394a90a268c	17677fc1-7a8f-916d-e063-6394a90a268c		1	HUMAN OTC DRUG LABEL	-	DETAILS	Regie Samuel	01-MAY-2024 15:55:41	-

### 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](mailto:CDERdirect@fda.hhs.gov)**.