



CDER *Direct*

Electronic Submissions Portal

**CDER Direct –
Blanket No Changes
Certification of Product Listing**

Blanket No Changes Certification

 U.S. Department of Health & Human Services

 **CDER** Direct
Electronic Submissions Portal

Step 1: Log into
your CDER
Direct Account



LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious

I Understand.

LOGIN

[Forgot your password?](#)

CDER Direct: direct.fda.gov

Blanket No Changes Certification

Step 3: Click on
“Create New/Upload
File”

Home > Product Listing and Reporting

SUBMISSIONS

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

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/SPL

PRODUCT LISTING AND REPORTING

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



GO

ACTIONS ▾

SEARCH PRODUCT

CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED	
SUBMISSION FAILED	30363785-1aca-3e10-e054-00144ffa2cc4	30363785-1acb-3e10-e054-00144ffa2cc4	cd7965321408.9360745821@direct	1	HUMAN COMPOUNDED DRUG LABEL		DETAILS	Puii Huber	11-APR-2016 09:31:34	-
SUBMISSION FAILED	215c5d91-45bc-1913-e054-00144ffa2cc4	215c5d91-45bd-1913-e054-00144ffa2cc4	cd9120835746.2674590831@direct	1	HUMAN OTC DRUG LABEL		DETAILS	Puii Huber	26-JAN-2016 11:56:18	-
DRAFT	de57f09b-895a-4c0b-ae81-010101db5004	215c5d91-45c3-1913-e054-00144ffa2cc4	-	7	HUMAN OTC DRUG LABEL	Walgreens 44-455C486	DETAILS	Puii Huber	05-OCT-2015 09:38:09	-
DRAFT	2155e182-b311-2f62-e054-00144ffa2cc4	2155e182-b312-2f62-e054-00144ffa2cc4	-	1	HUMAN OTC DRUG LABEL		DETAILS	Puii Huber	05-OCT-2015 02:15:40	-
SUBMISSION FAILED	208117c8-284f-5df0-e054-00144ffa7759	208117c8-2850-5df0-e054-00144ffa7759	cd7953804126.6391758240@direct	1	HUMAN OTC DRUG LABEL		DETAILS	Puii Huber	24-SEP-2015 15:07:29	-
SUBMISSION ACCEPTED	de57f09b-895a-4c0b-ae81-010101db5004	208f7410-5c85-129e-e054-00144ffa2cc4	cd1756420893.1803625479@direct	6	HUMAN OTC DRUG LABEL	Walgreens 44-455C486	DETAILS	Puii Huber	23-SEP-2015 15:00:29	-

Step 2: Click on “Product Listing and Certification”

Blanket No Changes Certification

SUBMISSIONS

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

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-identification

Product Listing and Certification

WDD/SPL

CREATE NEW PRODUCT LISTING

- Create a New Product Listing or Certification using a blank form
 Import an existing Product Listing or Certification SPL

SPL Document Type: *

Note: To update an existing submission, click Dashboard.

CONTINUE

CANCEL

-- Select Document Type --
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
BULK INGREDIENT
CELLULAR THERAPY
HUMAN COMPOUNDED DRUG LABEL
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG LABEL
NDC RESERVATION
NON-STANDARDIZED ALLERGENIC LABEL
PLASMA DERIVATIVE
STANDARDIZED ALLERGENIC
VACCINE LABEL

Step 4: Select the radio button “Create a New Product Listing or Certification using a blank form”

Step 5: Select the SPL Document Type – “Blanket No Changes Certification of Product Listing”

Blanket No Changes Certification

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 Certification submission form. Red asterisk indicate required fields.

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: * 5d04fd54-8101-a174-e053-2a91ab0a2f9e [Generate New](#)

Root ID: * 5d04fd54-8102-a174-e053-2a91ab0a2f9e [Generate New](#)

Effective Date: * 11-02-2017

AUTHORIZED AGENT DETAILS

Same as CDER Direct account details.

Organization DUNS: * 123456789

Organization Name: * Registrant Company

Phone Number: * 222-222-2222 [Format](#)

Step 6: Click the check box to auto populate Authorized Agent Details based on your CDER Direct account information

SEARCH

CDER Direct: direct.fda.gov

Blanket No Changes Certification

AUTHORIZED AGENT DETAILS

Same as CDER Direct account details.

Organization DUNS: * 000000000

Organization Name: * FDA

Phone Number: * 1-301-111-1111

ADD LABELER CODE

LABELER CODE:

ADD

Step 7: Click on “Add Labeler” button and enter the labeler code of the product(s) you wish to certify. Repeat step until you have all the labelers identified

LABELERS

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

* Click on the “Refresh Establishments” button

* Use check box in the report header for “Show All Establishments”

Step 8: Click on “Refresh Establishments” to find all the establishments that are involved with the Labeler(s) products

ADD LABELER

REFRESH ESTABLISHMENTS

CDER Direct: direct.fda.gov

Blanket No Changes Certification

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 any or all of the products

Step 9: Select the checkbox to choose all the establishments or just choose specific establishments. The establishment selected must be not be expired or inactivated.

LABELERS

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

- * Click on the "Refresh Establishments" button to update the establishments.
- * Use check box in the report header for "Select All" functionality.

<input type="checkbox"/>	LABELER CODE	NAME		
<input checked="" type="checkbox"/>	9999	DRLS Labeler	DRLS Team, 1-999-999-8888, drls@fda.hhs.gov	x

1 - 1

REFRESH ESTABLISHMENTS

ESTABLISHMENTS

Note: * Establishments

- * The list below includes only establishments that have not previously been included.
- * Use checkboxes to select establishments.



<input type="checkbox"/>	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	001230762 EXPIRED	DRLS Establishment	123 Main St, Herndon, VA, 20148, USA	John Doe, 1-732-720-2871, somemeail@email.com	

1 - 1 of 1

SHOW PRODUCTS

ADD ESTABLISHMENT

to be of confidential relationship. To add establishments that may have been submitted using this CDER Direct account, the confidential establishment will be

Blanket No Changes Certification

Step 11: Select the checkbox to choose the products you wish to certify. You can select all the products by checking the top checkbox.

SAVE / UPDATE

ADD PROD NDC

RETURN

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

Option to Select "ADD PROD NDC" to add a NDC product

<input checked="" type="checkbox"/>	PRODUCT NDC	PROPRIETARY NAME	MARKET	EXPIRATION DATE	FORM	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
<input checked="" type="checkbox"/>	9999-1115	Wonder Drug A	-	12-SEP-19	TABLET	ACETAMINOPHEN (500 m ⁺	Uncertified		-
<input type="checkbox"/>	9999-1195	Wonder Drug B	-	02-SEP-12	TABLET	CHLOROQUINE PHOSPHAT ⁺	Validation Errors		-
<input checked="" type="checkbox"/>	9999-1227	Wonder Drug C	-	02-SEP-12	TABLET	DICYCLOMINE HYDROCHL ⁺	Uncertified		-
<input type="checkbox"/>	9999-1282	Wonder Drug D	21-APR-10	02-SEP-12	TABLET	MEFLOQUINE HYDROCHLO ⁺	Completed		-
<input type="checkbox"/>	9999-2125	Wonder Drug A1	-	02-SEP-12	TABLET, COATED	CHLOROQUINE PHOSPHAT ⁺	Validation Errors		-
<input type="checkbox"/>	9999-6203	Wonder Drug A2	-	02-SEP-12	TABLET	ISONIAZID (300 mg)	Validation Errors		-

Blanket No Changes Certification

Home

Product Listing and Reporting

Products Certification



[Click here to get to know about certification process.](#)

Step 13: Submit 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: *

ae807bb4-d9f5-fe37-e053-2a95af0a0d2d

[Generate New](#)

Version Number: *

1

Root ID: *

ae807bb4-d9f6-fe37-e053-2a95af0a0d2d

[Generate New](#)

Effective Date: *

09-04-2020



Helpful Hints

- 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.
- Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.
- For more information, visit [Drug Listing Certification Quick Start Guide - FDA](#)
- <https://www.fda.gov/media/108725/download>

For more information

Log on to CDER Direct: direct.fda.gov

The CDER Direct portal currently works best with the following browsers:

- *Microsoft Edge*
- *Firefox version 28 and above*
- *Google Chrome*
- *Safari 10.0.1 and above*

Help Desk: CDERdirect@fda.hhs.gov