

# Annual Certification of Drug Product Listings

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# Agenda

- Background
- Who must certify and when?
- What must be certified?
- What will happen if a product is not certified?
- Challenge Questions

# Background



In 2016 – 21 CFR 207 was published (August) and implemented (November).

**21 CFR 207.57 (b)(2)** *For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single “no changes” certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.*

As a result, there is now an annual requirement to update your listing or certify that no changes have occurred, similar to registration requirements.

# Who Must Certify and When?



Since the legal responsibility for submitting product listing lies with the registered establishment, certification of product listing is also the responsibility of the registered establishments. Private label distributors can choose to submit the data directly.

Certification SPL submissions will **ONLY** be accepted during the annual listing certification period of October through December.



# What Must Be Certified?

During the annual listing certification period - October 1<sup>st</sup> – December 31<sup>st</sup>, every active listing on file that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the following year.

# When to Use the Blanket No Changes Certification



- ONLY when ALL the data on a listing SPL is still current:
  - Listing information contained in a Product Listing SPL is fully accurate, including establishment information
  - Quickly certify many drug products for a firm

# What Happens to an Uncertified Product?



Any NDC product code which has not been updated during the calendar year, or certified during the October to December registration renew period **will be considered expired** on January 1<sup>st</sup> of the following year.

All expired listings will be removed/notated in the NDC Directory and Unfinished Drug download files.

The only way to reinstate an expired listing is to submit an updated product listing SPL (with same SETID as previous version)

# How to Certify?

Step 1: Log into your [CDER Direct](#) Account

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

Home

Product Listing and Reporting

**SUBMISSIONS**  
(ADD SUBMISSION TYPE)

NDC/NHDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

**Product Listing and Certification**

WDO/JPL

**PRODUCT LISTING AND REPORTING**

For help with your SPL submission, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For questions related to Drug Establishment Registration and Product Listing, contact [eDRLS@fda.hhs.gov](mailto: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	
<a href="#">SUBMISSION FAILED</a>	30363785-1aca-3-e10-e054-00144fa2cc4	30363785-1acb-3e10-e054-00144fa2cc4	cd7965321408.9360745.8216@direct	1	HUMAN COMPOUNDED DRUG LABEL		<a href="#">DETAILS</a>	Pull Huber	11-APR-2016 09:31:34	-
<a href="#">SUBMISSION FAILED</a>	215c5d91-45bc-1913-e054-00144fa2cc4	215c5d91-45bd-1913-e054-00144fa2cc4	cd8120835745.2574590.8316@direct	1	HUMAN OTC DRUG LABEL		<a href="#">DETAILS</a>	Pull Huber	26-JAN-2016 11:56:58	-
<a href="#">DRAFT</a>	de5709b-895a-4c0b-ae01-010101d66004	215c5d91-45c3-1913-e054-00144fa2cc4	-	7	HUMAN OTC DRUG LABEL	<a href="#">Walgreens 44-455C386</a>	<a href="#">DETAILS</a>	Pull Huber	05-OCT-2015 09:38:09	-
<a href="#">DRAFT</a>	2155e182-a311-2f62-e054-00144fa2cc4	2155e182-a312-2b62-e054-00144fa2cc4	-	1	HUMAN OTC DRUG LABEL		<a href="#">DETAILS</a>	Pull Huber	05-OCT-2015 02:15:40	-
<a href="#">SUBMISSION FAILED</a>	208117a8-284f-5d80-e054-00144fa2cc4	208117a8-2850-5d80-e054-00144fa2cc4	cd7963084126.6391758.240@direct	1	HUMAN OTC DRUG LABEL		<a href="#">DETAILS</a>	Pull Huber	24-SEP-2015 15:07:29	-
<a href="#">SUBMISSION ACCEPTED</a>	de5709b-895a-4c0b-ae01-010101d66004	20607410-5c05-129e-e054-00144fa2cc4	cd1766420893.1803625.475@direct	6	HUMAN OTC DRUG LABEL	<a href="#">Walgreens 44-455C416</a>	<a href="#">DETAILS</a>	Pull Huber	23-SEP-2015 15:07:29	-

1 - 8

Step 2: Click on  
“Product  
Listing and  
Certification”



# How to Certify?

SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/3PL

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

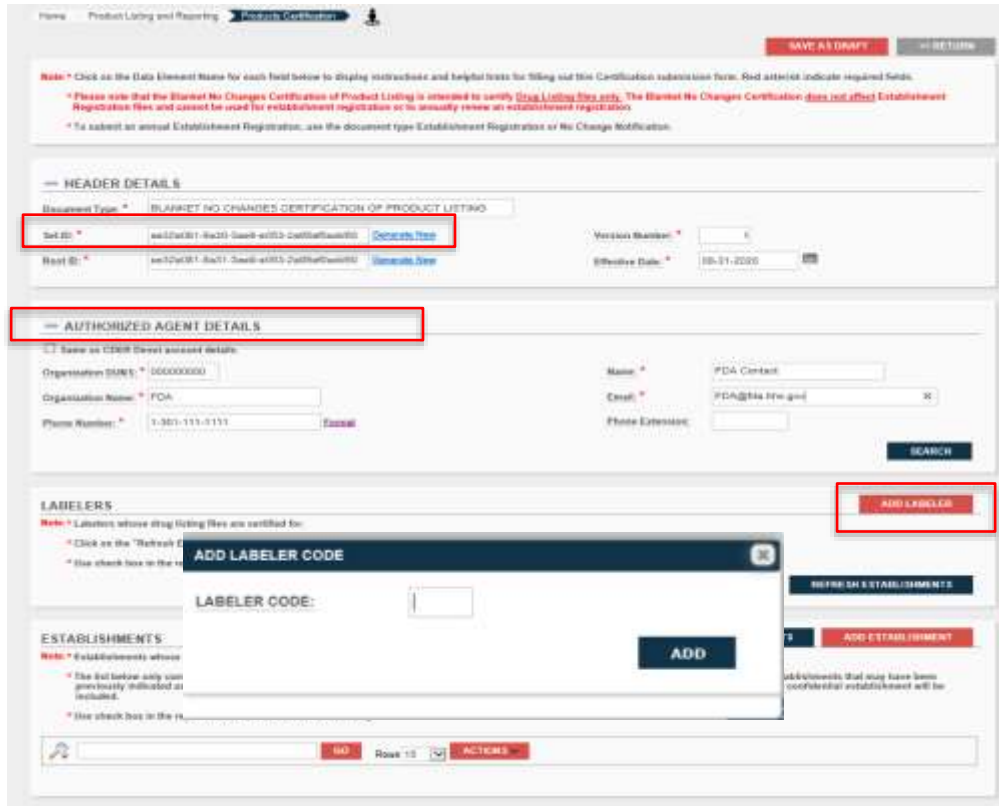
STANDARDIZED ALLERGENIC

VACCINE LABEL

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

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

# How to Certify?



Home Product Listing and Reporting Products 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.

\* 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: \* ea22ac81-8a23-3a68-a053-2a08a0a0a0a0 [Generate New](#)

Root ID: \* ea22ac81-8a23-3a68-a053-2a08a0a0a0a0 [Generate New](#)

Version Number: \* 1

Effective Date: \* 08-31-2020

→ AUTHORIZED AGENT DETAILS

U.S. State or CDER Direct account details:

Organization SUNE: \* 000000000

Organization Name: \* FDA

Phone Number: \* 1-301-111-5111 [Cancel](#)

Name: \* FDA Contact

Email: \* FDA@fda.hhs.gov

Phone Extension:

SEARCH

LABELERS

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

\* Click on the "Refresh" button.

\* Use check box to the right of the labeler code.

ADD LABELER CODE

LABELER CODE: [ ]

ADD

REFRESH ESTABLISHMENTS

ADD ESTABLISHMENT

ESTABLISHMENTS

**Note:** Establishments whose:

\* The list below only you previously indicated as included.

\* Use check box to the right of the establishment name.

ADD

100 Row(s) ACTIONS

Because this is a single submission every year, you can use the auto generated SET ID and Root ID.

Step 6: Authorized Agent is generally the same as CDER Direct account owner

Click on “Add Labeler” button and enter the labeler code of the product(s) you wish to certify. Once you have all the labelers identified, click on “Refresh Establishments” to find all the establishments that are involved with the Labeler(s) products.

# How to Certify?



**LABELERS** ADD LABELER

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

- \* Click on the "Refresh Establishments" button to update the establishment list based on the labeler selection.
- \* Use check box in the report header for "Select All" functionality.

<input type="checkbox"/>	LABELER CODE	NAME	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	0000	ORLS Labeler	ORLS Team, 1-800-900-8888, <a href="mailto:orls@cdela.hhs.gov">orls@cdela.hhs.gov</a>	

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.

GO Rows: 15 ACTIONS

<input type="checkbox"/>	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS	DELETE
<input checked="" type="checkbox"/>	001230762 <span>EXPIRED</span>	ORLS Establishment	123 Main St, Herndon, VA, 20148, USA	John Doe, 1-732-720-2871, <a href="mailto:somemoremail@gmail.com">somemoremail@gmail.com</a>	

1 - 1 of 1

# Understanding Product Status

## PRODUCTS

[SAVE / UPDATE](#)[ADD PROD NDC](#)[RETURN](#)

**Note:** By selecting a product ndc certifies the product across all root id's. If you don't find your Product NDC in the list, you can add it using the "Add Prod NDC"

Filter products by Establishments: Show All 

### STATUS:

**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 ISET 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



[GO](#) Rows  15 [ACTIONS](#) 

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

1 - 6 of 6

# Understanding Product Status



**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, if it remains in the market with no change to previous data.

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

# Understanding Product Status



**Completed:** Product is discontinued.

**Current:** The listing data for this product was either submitted or revised in the current calendar year.

**Validation Errors:** The current version of the previously submitted product listing file does not conform to current validation procedures.

# Understanding Product Status



**Inactivated:** The listing data for this product has been inactivated by FDA.

**Expired:** The listing data is expired because it was not certified to be current.

# Validation Errors Identified

Validation Errors

This product is not available for certification. You must access the listing SPL (58e0d2fc-a87f-4259-a1b1-e36d24d11c80), make all the required corrections and re-submit. An update to the listing SPL will satisfy your annual product certification requirement.

Please refer to the latest Structured Product Labeling (SPL) Implementation Guide with Validation Procedures to find these violated Validation Procedures indicated here by their section numbers.

RULE ID	RULE TEXT
4.1.5.1	If the product is regulated by CDER, then an establishment operation listed is linked to at least one listed product or part product, except for Human Compounded Drug Label (75031-5).
4.1.5.2	If the product is regulated by CDER, then each listed product having an active marketing status is linked from at least one establishment operation, except for Human Compounded Drug Label (75031-5).


1 - 2

5-400			01-JAN-98	SOLUTION	CHLORHEXIDINE GLUCON+	<a href="#">Validation Errors</a>
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# Certifying Product NDC













SAVE / UPDATE



GO


Rows 15

ACTIONS

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

1 - 6 of 6

# Submit SPL: BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING

[Home](#) > [Product Listing and Reporting](#) > [Products Certification](#) >  [Click here to get to know about certification process.](#)

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



# Frequently Asked Questions



- **Should I use the same SET ID to update a blanket no changes certification?**
  - 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. However, you may add new NDCs to be certified with a new SET ID.

# Frequently Asked Questions



- **Does this blanket no changes certification renew my establishment registration status?**
  - No, these are two separate renewals. The blanket no changes certification SPL is to certify drug listings only.

# Frequently Asked Questions



- What if my product has an end marketing date and completed status, does it need to be certified?
- Do I need to certify my product if it has a future marketing date?
- These questions and more are answered on the eDRLS website

<https://www.fda.gov/edrls>

## Blanket No Change Certification for Product Listing Data UPDATED

Within the new regulations adopted in 2016, there is now an annual requirement to update your listings or certify that no changes have occurred for products that were not initially listed or updated during the past calendar year - January 2017 to the present. The period for Product Listing Certification using the Product Listing Certification SPL submission is October 1st through December 31st. Any product listing that is required to be certified but not certified, may be considered inactive and removed from the NDC Directory and other publications of Listing data. Outside this three month window an update of the Listing SPL submission for each NDC is required to certify the product. [Product Listing Certification Guide \(PDF - 534KB\)](#)

Drug Registration and Listing System (DRLS and eDRLS)

Electronic Drug Registration and Listing Instructions

Electronic Registration and Listing Compliance Program

Dun and Bradstreet Verification

Points of Contact for Drug Registration and Listing



# Challenge Question 1

Blanket No Changes Certification SPL must be submitted

1. June and December
2. Anytime
3. As soon as there's any change.
4. October 1 – December 31

# Challenge Questions

- If I listed or updated a product in the current calendar year, do I need to ensure that I certify that product between Oct. 1 - Dec. 31?
  - Yes
  - No

# Summary

- **Every active listing on file** with the FDA that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the coming year.
- Certification SPLs are only submitted during the annual listing certification period October 1 – December 31
- Products that are not certified will be considered expired and removed from publication on January 1 of the following year.
- Products that are expired, delisted, or have a listing deficiency or “validation errors” cannot be certified and must be updated with a full product listing SPL
- Products under the category of “Unapproved Drug for use in Drug Shortage” cannot be certified





***Thank You for  
Keeping Your Drug  
Listings Up-to-Date!***