

Product Listing Certification Guide

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. Outside this window an update of the Listing SPL submission for each NDC is required to certify the product.

Who must certify and when?

- Since the ultimate responsibility for submitting product listings lies with the registered establishment, certification of product listings is also the responsibility of the registered establishments.
- Private Label Distributors (PLDs) and Contract Manufacturers (CMs) should work together to ensure that all NDCs involved in their business relationships are properly certified.
- US Agents, Importers, Consultants, and anyone acting as an authorized agent for a registrant may submit product listing certification SPL files.
- Certification SPL submissions will ONLY be accepted during the registration renewal period of October 1 through December 31. Outside that window, individual product listing SPLs must be used to update (or renew) a listing.

What must be certified?

During the reregistration period - October 1st – December 31st, 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.

- **Includes all human drug document/product types and marketing categories including:**
 - **Finished and unfinished/bulk/API listings**
 - **Approved and unapproved listings**
 - **Rx and OTC listings**
 - **Medical Gases, Homeopathics, Bulk drugs for human drug compounding**
 - **PLD and contractor listings**
 - **Repackaged and relabeled listings**
- Any NDC Product code for which a listing submission, new or updated, has been received during the calendar year is considered to be up-to-date and *does not need to be certified*.

- Only electronic (SPL) listings can be certified. Any drug last updated in paper prior to June 2009 must first be submitted electronically. (However, a full listing submission therefore counts as an update and satisfies the certification requirement.)

Note: Veterinary product listings must be certified, but follow a different process for certification. Please contact CVM for more information.

What am I certifying?

Certification of an NDC product code is a statement that **all product data** has been reviewed and deemed accurate and up-to-date. Includes but not limited to:

- **All packaging presentations**
- **Labeling**
- **Dosage Form**
- **DEA Schedule**
- **Formulation**
- **Product listings with a known data deficiency identified by FDA cannot be certified. A full product listing SPL correcting the error/deficiency must be submitted. (However, a full listing submission therefore counts as an update and satisfies the certification requirement.)**
- **Discontinued/delisted or expired listings cannot be certified. A full product listing SPL correcting the error/deficiency must be submitted. (However, a full listing submission therefore counts as an update and satisfies the certification requirement.)**

What happens if a product is not certified?

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 1st of the following year.

All expired listings will be removed from publication 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, Different Document ID, One higher version number than the most recent submission).

Communication of expired listings to the NDC SPL Data Elements (NSDE) file or DailyMed is planned and will be in place by December 31st, 2017.

Frequently Asked Questions

- **What, if any, will be the penalty for noncompliance (other than the obvious that the product listing will be designated as expired and reflected as such in the relevant databases)?**
 - Without speaking to a penalty for any specific or hypothetical case, a product that is still actively marketed and sold without being properly listed is in direct violation of 21 CFR 207 and will be considered misbranding.
- **What happens if I certify a product that has already been certified by someone else?**
 - Nothing happens. There is no problem. Certifying the product twice or more will have no effect on anything.
- **What are all the different statuses associated with certifying a product listing?**
 - **Certified** – This product has already been certified for the current year.
 - **Pending** - This product has not been certified yet.
 - **Pending Compliance Case** - There is a compliance case pending and this product cannot be certified.
 - **Expired/Completed** - This product has passed its marketing end date and cannot be certified.
 - **Current** - A new version has been received this year and the Product does not need to be certified.
- **What if my product has an end marketing date and completed status, does it need to be certified?**
 - No, if the product has an end marketing date and has completed status, it does not need to be certified.
- **Do I need to certify my product if it has a future marketing date?**
 - Yes
- **What SET ID do I use?**
 - Every year you will use a new SET ID. So your first (maybe only) Product Listing Certification SPL will use the auto-generated SET ID. If you send in another submission during the certification period, you would use the same SET ID, a new ROOT ID and a version number at least 1 higher than the last submission.

How to certify your product listings

Below are screenshots showing how to certify listings using **CDERDirect**.

For information on using “Blanket No Changes Certification of Product Listing” in **SPL Xforms**:
<https://www.fda.gov/forindustry/datastandards/structuredproductlabeling/ucm189651.htm>

For users of other systems, please contact your vendor.

Steps to Certify Product Listings in CDERDirect

1. Login to CDERDirect
2. Select Product Listing and Certification
3. Select "Create New/Upload File"
4. Select the radio button "Create a New Product or Certification using a blank form".
5. Choose the Product Document Type – "Blanket No Changes Certification of Product Listing"
6. Complete the Authorized Agent Information. There is a checkbox if the CDERDirect account belongs to the authorized agent.
7. Select the ADD LABELER button and enter the labeler code of the products you wish to certify. Continue until you have all the labelers identified.
8. Refresh the establishments to find all the establishments that are involved with the identified labelers products.
9. Select the top checkbox to choose all the establishments or just choose specific establishments.
10. You can also add any establishments you wish at this point.
11. Once you have your establishments marked you should select "Show Products" This will result in a list of products.
12. At this point you can add NDC's that do not show up but require your certification.
13. You can choose to certify all or any of the products. The top checkbox gives you the ability to choose ALL products.
14. Once all products you choose to certify have been marked, save the SPL and send the submission to the FDA.

If you need a CDERDirect account, you can get one by going to <https://direct.fda.gov> . Once there, click on the “Create Account” Tab to the right.

Below are some screenshots and help text to guide you through the process.

Log into CDERDirect and Select “Product Listing and Certification”

The screenshot displays the CDER Direct Electronic Submissions Portal. The page header includes the U.S. Department of Health & Human Services logo and the CDER Direct logo. The user is logged in as DONDUCCAN - FDA, EDRLS. The left sidebar contains navigation options: SUBMISSIONS (with 'Product Listing and Certification' selected), MANAGE ACCOUNT, and WDOGPL. The main content area shows a table of ALL SUBMISSIONS.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
DRAFT	5c4c0b0-36cb-c0d-f4053-2991aa0a7569	5c4c0b0-36cb-c0d-f4053-2991aa0a7569		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Regie Samuel	24-OCT-2017 10:39:47	
DRAFT	5b7fa3-b43e-23e-c-e053-2a91aa0a290b	5b7fa3-b43e-23e-c-e053-2a91aa0a290b		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Paul Loebach	23-OCT-2017 16:24:32	
DRAFT	5bc463ad-e0e9-6c14-e053-2a91aa0a3871	5bc463ad-e0e9-6c14-e053-2a91aa0a3871		1	HUMAN OTC DRUG LABEL	Don Duggan	17-OCT-2017 15:40:56	
DRAFT	5bc0883-2898-e106-e053-2a91aa0a2c9e	5bc0883-2898-e106-e053-2a91aa0a2c9e		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Regie Samuel	17-OCT-2017 11:47:04	
DRAFT	5bc03e4-6c89-15b-b-e053-2991aa0a2c04	5bc03e4-6c89-15b-b-e053-2991aa0a2c04		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Troy Cu	17-OCT-2017 11:09:54	
DRAFT	5b3542a3-7ea7-a5ee-e053-2991aa0a1a1c3	5b3542a3-7ea7-a5ee-e053-2991aa0a1a1c3		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Don Duggan	10-OCT-2017 13:17:32	
DRAFT	5ac0646-e28f-6c9-3-e053-2a91aa0ad1fa	5ac0646-e28f-6c9-3-e053-2a91aa0ad1fa		1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Paul Loebach	05-OCT-2017 11:23:41	
DRAFT	576802b-4ec9-b41d-e053-2a91aa0a0da2	576802b-4ec9-b41d-e053-2a91aa0a0da2		1	BULK INGREDIENT	Paul Loebach	28-SEP-2017 13:37:48	
DRAFT	a1095641-4291-4676-a395-11762988	568f18f-65ba-147b-5691aa0a0a0a0a0a		4	HUMAN OTC DRUG LABEL	Troy Cu	20-SEP-2017	

U.S. Department of Health & Human Services
FDA CDER Direct
 Electronic Submissions Portal

Welcome DONDUIGGAN - FDA_EDRLS | Logout

Home > Product Listing and Reporting

SUBMISSIONS

- NDC/NHRC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- WDOIGPL

PRODUCT LISTING AND REPORTING

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	
DRAFT	5c4c8bc0-36cb-d0af-e053-2991aa0a7569	5c4c8bc0-36cb-d0af-e053-2991aa0a7569	-	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Regie Samuel	24-OCT-2017 10:39:47	-
DRAFT	5b7fa43-b43e-23ec-e053-2a91aa0a2668	5b7fa43-b43e-23ec-e053-2a91aa0a2668	-	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Paul Loebach	23-OCT-2017 16:24:32	-
DRAFT	5bc403ad-e0b0-4c14-e053-2a91aa0a3871	5bc403ad-e0b0-4c14-e053-2a91aa0a3871	-	1	HUMAN OTC DRUG LABEL	DETAILS	-	Don Duggan	17-OCT-2017 15:40:56	-
DRAFT	5bc0983-2898-d106-e053-2a91aa0a039e	5bc0983-2898-d106-e053-2a91aa0a039e	-	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Regie Samuel	17-OCT-2017 11:47:04	-
DRAFT	5bc03be4-6c19-158b-e053-2991aa0a2c54	5bc03be4-6c19-158b-e053-2991aa0a2c54	-	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Troy Cu	17-OCT-2017 11:09:54	-
DRAFT	5b3542a3-7ea7-a6ee-e053-2991aa0a01c3	5b3542a3-7ea7-a6ee-e053-2991aa0a01c3	-	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Don Duggan	10-OCT-2017 13:17:32	-
DRAFT	5768d7b-4ac9-b41d-e053-2a91aa0a0da2	5768d7b-4ac9-b41d-e053-2a91aa0a0da2	-	1	BULK INGREDIENT	DETAILS	-	Paul Loebach	28-SEP-2017 13:37:48	-
DRAFT	a10054c1-4291-4676-a394-117a20a825a	568f18f-55ba-1478-e054-0014489546c	-	4	HUMAN OTC DRUG LABEL	Label Data DETAILS	-	Troy Cu	20-SEP-2017 11:19:19	-

11:58 AM 10/25/2017

Select "Create New/Upload File"

U.S. Department of Health & Human Services
FDA CDER Direct
 Electronic Submissions Portal

Welcome DONDUIGGAN - FDA_EDRLS | Logout

SUBMISSIONS

- NDC/NHRC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- WDOIGPL

CREATE NEW PRODUCT LISTING

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

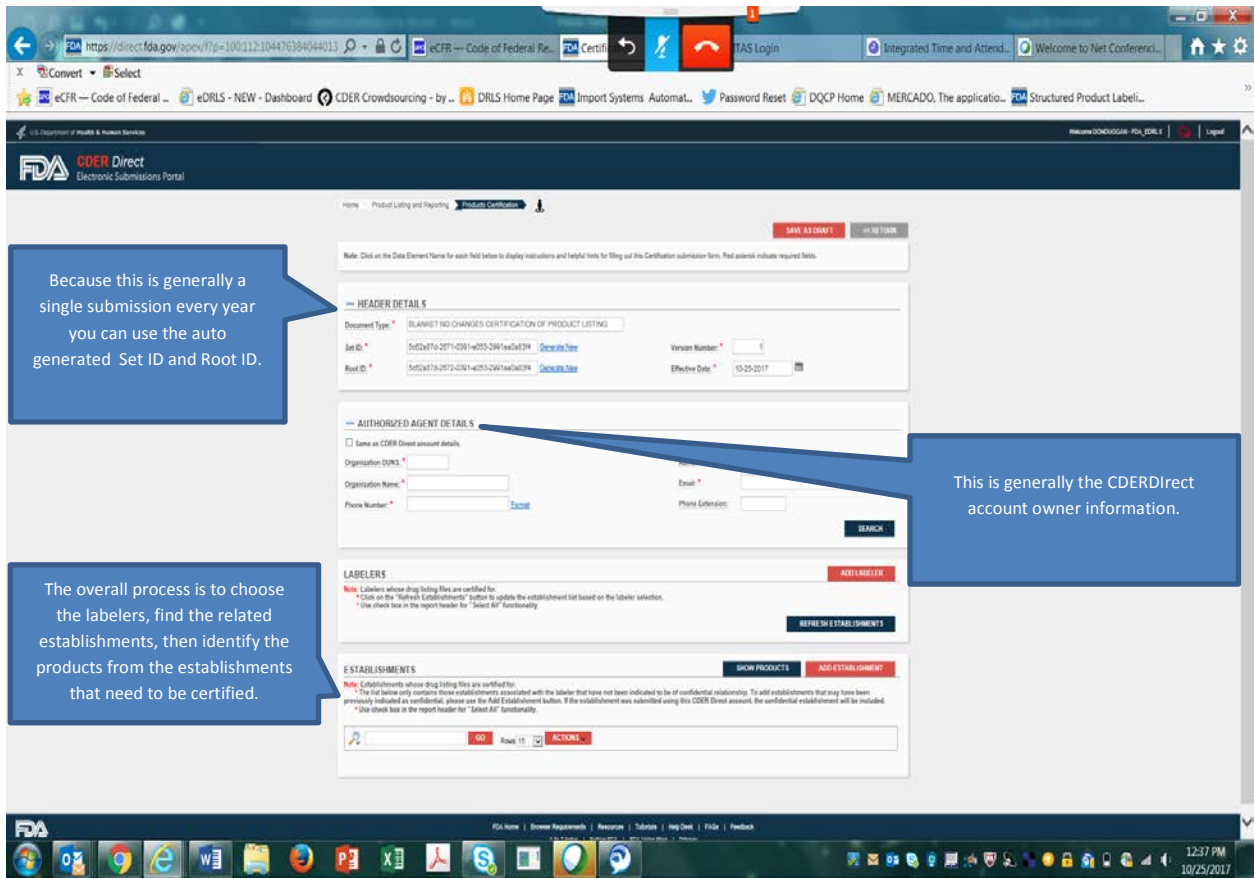
Product Document Type: **-- Select Document Type --**

- BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
- BULK INGREDIENT
- CELLULAR THERAPY
- DRUG FOR FURTHER PROCESSING
- HUMAN COMPOUNDED DRUG LABEL
- HUMAN OTC DRUG LABEL
- HUMAN PRESCRIPTION DRUG LABEL
- NON-STANDARDIZED ALLERGENIC LABEL
- PLASMA DERIVATIVE
- STANDARDIZED ALLERGENIC
- VACCINE LABEL

CONTINUE CANCEL

Note: To update an existing submission, go to the Product Listing and Reporting Dashboard.

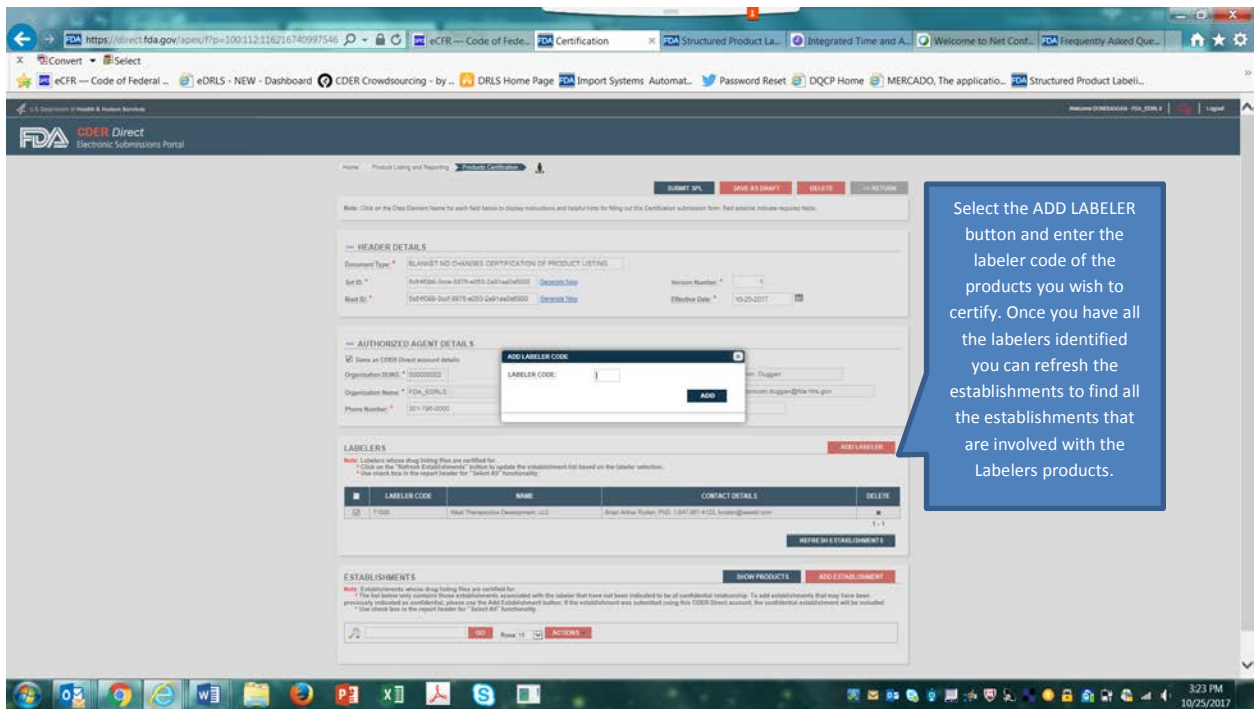
Select the radio button "Create a New Product or Certification using a blank form". Choose the Product Document Type – "Blanket No Changes Certification of Product Listing"



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

The overall process is to choose the labelers, find the related establishments, then identify the products from the establishments that need to be certified.

This is generally the CDER Direct account owner information.



Select the ADD LABELER button and enter the labeler code of the products you wish to certify. Once you have all the labelers identified you can refresh the establishments to find all the establishments that are involved with the Labelers products.

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

Select "Refresh Establishments" once you have your labeler code(s)

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.

Select "ADD PROD NDC" to add a NDC product

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

After you have selected the products you wish to certify select the "SAVE/UPDATE" and then you can submit the file to the FDA.