

Annual Certification of Drug Product Listings

October 5, 2017

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FDA/CDER/Office of Compliance

Drug Listing Certification

- *Background – regulatory, problems encountered, new regulatory requirement*
- *Who must certify, what must be certified, and when do they do it?*
- *What will happen if a product is not certified?*
- *What does certification look like (from CDER Direct)?*



Listing Certification Background

To start with, here's what companies are required to do:

Section 510(j)(2)(B) of the Food Drug And Cosmetic Act requires that registrants to delist any discontinued product on file every June or December

Section 510(j)(2)(D) of the Food Drug And Cosmetic Act requires that registrants to send in any material changes to any listing already on file every June or December .

- Established the statutory requirement to keep listings up to date
- Previous version of 21 CFR 207.30 echoed that requirement but also added that if no changes have occurred, no report or update is required.

Listing Certification Background – cont'd



Despite the requirements, here's what companies are actually doing:

- Many companies will list a product initially, then never update again.
 - One time import
 - Don't know about update requirements, or aren't as concerned with keeping all data up to date so long as imports processing, reimbursement, and insurance payments continue.
 - Company may go out of business with no one left to submit discontinuances
- Have to consider non-updated listings as active
 - Electronic listings back to 2010
 - **Paper listings as far back as early to mid 1990's!**

Listing Certification Background - contd



In 2016 – a new 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.

Listing Certification



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 through December.

Outside that window, individual product listing SPLs must be used to update (or renew) a listing.

Listing Certification



What must be certified?

*At the time of reregistration in the Fall, **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, Bulks 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.

Note: *Veterinary product listings must be certified, but follow a different process for certification.*

*Only electronic (SPL) listings can be certified. **Any drug last updated in paper prior to June 2009 must first be submitted electronically.** (which therefore counts as an update and satisfies the certification requirement!)*

Listing Certification



What must be certified? -cont'd

*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*
- DEA Schedule*

*Only electronic (SPL) listings can be certified. **Any drug last updated in paper prior to June 2009 must first be submitted electronically.** (which therefore counts as an update and satisfies the certification requirement!)*

*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. (which 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. (which therefore counts as an update and satisfies the certification requirement!)*

Listing Certification



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)

Communication of expired listings to the NDC SPL Data Elements (NSDE) file or DailyMed is planned but as yet has not been worked out with those offices.

Listing Certification

What does certification look like?

U.S. Department of Health & Human Services

Welcome TRAVIS1234 - DRUG M@KERS | [Feedback Logo](#) | [Logout](#)

FDA **CDER Direct**
Electronic Submissions Portal

SUBMISSIONS

- NDC/NHRIC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Recertification
- WDD/3PL

CREATE NEW PRODUCT LISTING

☒ Create a New Product Listing or Report using a blank form
☐ Import an existing Product Listing or Report SPL

Product Document Type: *
-- Select Document Type --
-- Select Document Type --
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
HUMAN COMPOUNDED DRUG LABEL
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG LABEL

Note: To update an existing submission, click on the submission ID in the table below. [ACCEPTED from the table in the prior page /](#)

[CONTINUE](#) [CANCEL](#)

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 Re-Certification submission form. Red asterisk indicate required fields.

— HEADER DETAILS

Document Type: * BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING

Set ID: * 57fafd27-c44b-70d4-e053-0791b40a5619 [Generate New](#)

Version Number: * 1

Root ID: * 57fafd27-c44c-70d4-e053-0791b40a5619 [Generate New](#)

Effective Date: * 08-30-2017 

— AUTHORIZED AGENT DETAILS

☐ Same as CDER Direct account details.

Organization DUNS: *

Agent Name: *

Organization Name: *

Email: *

Phone Number: * [Format](#)

Phone Extension: *

SEARCH

LABELERS

[ADD LABELER](#)

Note: 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.

[REFRESH ESTABLISHMENTS](#)

ESTABLISHMENTS

[SHOW PRODUCTS](#)
[ADD ESTABLISHMENT](#)

Note: 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/Unselect All" functionality.



[GO](#)
[ACTIONS](#)
[Format](#)
[SEARCH](#)
[ADD LABELER](#)
[REFRESH ESTABLISHMENTS](#)
[SHOW PRODUCTS](#)
[ADD ESTABLISHMENT](#)

Add Labeler



Add Labeler Code:

[ADD](#)

ents associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

Once the labeler code is manually added, the establishments that are associated with the products listed by the labeler show up under the Establishments. If they are marked confidential in the products listed with this labeler NDC, then the user can click on ADD Establishment to add Establishment.

AUTHORIZED AGENT DETAILS

☐ Same as CDER Direct account details.

Organization DUNS:

Organization Name:

Phone Number:

Agent Name:

Add Establishment

Add Establishment DUNS:

ADD

SEARCH

LABELERS

ADD LABELER

REFRESH ESTABLISHMENTS

ESTABLISHMENTS

SHOW PRODUCTS

ADD ESTABLISHMENT

Note: 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.

Note: 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/Unselect All" functionality.

GO

ACTIONS

Once the establishment is added click on Show Products to view the products associated with the DUNS

Home

Product Listing and Reporting

Products Re-Certification

Products

PRODUCTS

SAVE / UPDATE

ADD PROD NDC

RETURN

Note: By selecting a product ndc certifies the product across all root id's.

GO

ACTIONS

PRODUCTS

SAVE / UPDATE

ADD PROD NDC

RETURN




















Note: By selecting a product ndc certifies the product across all root id's.



GO

Rows 100 

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"/>	11014-0214	Pirfenidone	-	16-FEB-16	CAPSULE	PIRFENIDONE 267 mg	Pending		
<input type="checkbox"/>	27437-106	Alinia	-	16-FEB-16	POWDER, FOR SUSPENSION	NITAZOXANIDE 100 mg/..+.	Pending		
<input type="checkbox"/>	47682-037	Private Label Distributor	-	16-FEB-16	TABLET, FILM COATED	NAPROXEN SODIUM 220 ..+.	Pending		
<input type="checkbox"/>	47682-237	Medique Mediproxen	-	16-FEB-16	TABLET, FILM COATED	NAPROXEN SODIUM 220 ..+.	Pending		
<input type="checkbox"/>	53746-109	Hydrocodone Bitartrate and Acetaminophen	-	16-FEB-16	TABLET	ACETAMINOPHEN; HYDRO..+.	Pending		
<input type="checkbox"/>	53746-110	Hydrocodone Bitartrate and Acetaminophen	-	15-FEB-16	TABLET	ACETAMINOPHEN; HYDRO..+.	Pending		
<input type="checkbox"/>	53746-116	Hydrocodone Bitartrate and Ibuprofen	-	15-FEB-16	TABLET	HYDROCODONE BITARTRA..+.	Pending		
<input type="checkbox"/>	53746-117	Hydrocodone Bitartrate and Ibuprofen	-	15-FEB-16	TABLET	HYDROCODONE BITARTRA..+.	Pending		
<input type="checkbox"/>	53746-145	Hydrocodone Bitartrate and Ibuprofen	-	15-FEB-16	TABLET	HYDROCODONE BITARTRA..+.	Pending		
<input type="checkbox"/>	53746-146	Hydrocodone Bitartrate and Ibuprofen	-	15-FEB-16	TABLET	HYDROCODONE BITARTRA..+.	Pending		
<input type="checkbox"/>	53746-169	Memantine hydrochloride	-	15-FEB-16	TABLET, FILM COATED	MEMANTINE HYDROCHLOR..+.	Pending		
<input type="checkbox"/>	53746-173	Memantine hydrochloride	-	15-FEB-16	TABLET, FILM COATED	MEMANTINE HYDROCHLOR..+.	Pending		
<input type="checkbox"/>	53746-203	Oxycodone and Acetaminophen	-	16-FEB-16	TABLET	ACETAMINOPHEN; OXYCO..+.	Pending		
<input type="checkbox"/>	53746-204	Oxycodone and Acetaminophen	-	15-FEB-16	TABLET	ACETAMINOPHEN; OXYCO..+.	Pending		
<input type="checkbox"/>	53746-226	Estradiol	-	16-FEB-16	INSERT	ESTRADIOL 10 ug	Pending		
<input type="checkbox"/>	65162-006	Amlodipine Besylate	-	16-FEB-16	TABLET	AMLODIPINE BESYLATE ..+.	Pending		
<input type="checkbox"/>	65162-006	Amlodipine Besylate	-	16-FEB-16	TABLET	AMLODIPINE BESYLATE ..+.	Pending		
<input type="checkbox"/>	65162-007	Amlodipine Besylate	-	16-FEB-16	TABLET	AMLODIPINE BESYLATE ..+.	Pending		
<input type="checkbox"/>	65162-007	Amlodipine Besylate	-	16-FEB-16	TABLET	AMLODIPINE BESYLATE ..+.	Pending		

Listing Certification *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 re-registration period October – December*
- *Products that are not certified will be considered expired and removed from publication*
- *Products that are expired, delisted, or have a listing deficiency 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*



Listing Certification

Questions?

Thank you