Blanket No Change Certification

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Learning Objectives

- Describe the listing certification requirements
- Identify who needs to certify
- CDER Direct Demonstration

What are Listing Certification Requirements?

- Each drug not initially listed/updated during the calendar year must be updated or certify that the data has not changed since the last update (21 CFR 207.57(b)(2))
- Blanket No Change SPL:
  - Available during the annual period of drug listing certification window
  - October 1 – December 31
- Blanket No Change SPLs will only be accepted during the annual certification window

What are Listing Certification Requirements?

- Outside of window, update of the drug listing SPL submission for each NDC is required for certification
  - Drug listing SPLs received for NDCs during the current calendar year are considered up-to-date and do not require additional certification
- Drug listings not certified will be considered expired and may be inactivated and removed from NDC Directory and DailyMed
  - Only way to restore listing to submit an updated full product listing SPL (with the same SET ID)

Who Needs to Certify?

- Certification of drug listings is responsibility of registered establishments
- Authorized agents for registered establishments may submit certification SPL files for drug listings
  - Private Label Distributors
  - Vendors
  - U.S. agents

Demonstration

Blanket No Change Certification Demonstration

https://direct.fda.gov

CDER Direct
Electronic Submissions Portal

Home

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- NDC Reservation
- WDDOPL

MANAGE ACCOUNT

- Edit User Profile
- Manage Users

ALL SUBMISSIONS

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.

GO | ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	ca643fb2-7c36-8131-e053-2995af0a3854	caf39dd3-8447-c128-e053-2995af0a804e	cd347168529 9042763156@ direct	4	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 14:01:10
SUBMISSION ACCEPTED	ca643fb2-7c36-8131-e053-2995af0a3854	caf39dd3-8445-c128-e053-2995af0a804e	cd4865173209 7824601593 @direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 13:51:09
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	caf1dcf3-3438-14f5-e053-2a95af0ad3d1	cd6253017498 5436017825 @direct	3	ESTABLISHMENT DE-REGISTRATION	Vikas Arora	01-SEP-2021 11:45:12
SUBMISSION ACCEPTED	ca643fb2-7c36-8131-e053-2995af0a3854	ca7a5104-3203-5f89-e053-2995af0ac7f5	cd6183047925 3257091648 @direct	2	ESTABLISHMENT REGISTRATION	Vikas Arora	27-AUG-2021 13:27:03
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	ca7a45ff-eef0-738a-e053-2a95af0a0b58	cd4012596387 7438216905 @direct	2	ESTABLISHMENT REGISTRATION	Vikas Arora	27-AUG-2021 13:27:03
SUBMISSION ACCEPTED	ca643fb2-7c36-8131-e053-2995af0a3854	ca643fb2-7c36-8131-e053-2995af0a3854	cd6732409851 7568203914 @direct	1	ESTABLISHMENT REGISTRATION	Vikas Arora	26-AUG-2021 09:56:49
SUBMISSION ACCEPTED	ca5028b4-e845-0b05-e053-2a95af0af82a	ca5028b4-e846-0b05-e053-2a95af0af82a	cd1480697532 3674218905 @direct	1	ESTABLISHMENT REGISTRATION	Vikas Arora	26-AUG-2021 09:56:49

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Contact Help Desk

You have selected 1 Establishments.

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 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.

GO | Rows 15 | ACTIONS

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	DELETE
☐	55555-111	WonderPatch	-	26-MAR-22	PATCH	SALICYLIC ACID (40 1+	Uncertified	-
☐	55555-222	WonderGel	-	26-MAR-22	GEL	SALICYLIC ACID (40 1+	Uncertified	-
-	55555-333	Wonderdrug	-	26-MAR-22	TABLET	COAL TAR (200 mg)	Inactivated	-
☐	55555-777	Wonderdrug	-	26-MAR-22	TABLET	COAL TAR (2000 mg)	Uncertified	-
☐	55555-999	Wondercream	-	26-MAR-22	CREAM	COAL TAR (5 g/100 g)+	Uncertified	-

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Contact Help Desk

Challenge Question #1

True or False: Blanket No Change Certifications can be completed at any time of the year.

True

False

Challenge Question #2

True or False: Private Label Distributors (PLD) can act as authorized agents on behalf of the establishment for a PLD's drug listing and certification requirements?

True

False

Summary

- During the calendar year, drug listings must be updated via a new SPL submission, or certified through a Blanket No Change Certification that the data has not changed since the last update.
- If the October 1 – December 31 annual certification window is passed, a new SPL submission is required in order to certify a listing.
- **Please keep your drug listings current!**

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

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