

# **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 <u>expired</u> 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



### SUBMISSIONS (ADD SUBMISSION TYPE)

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

#### MANAGE ACCOUNT

Edit User Profile

Manage Users

#### **ALL SUBMISSIONS**

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

GO AC

STATUS	SET ID	SET ID ROOT ID SUBMISSION UVERSION DOCUMENT LABEL			LAST MODIFIED USER	LAST MODIFIED DATE		
SUBMISSION ACCEPTED	ca643fb2-7c35-8131- e053-2995af0a3854	caf39dd3-8447-c128- e053-2995af0a804e	cd347168529. 9042763158@ direct	4	ESTABLISHMENT DE- REGISTRATION	Vikas Arora	01-SEP-2021 14:01:10	
SUBMISSION ACCEPTED	ca643fb2-7c35-8131- 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 .9436017825 @direct	3	ESTABLISHMENT DE- REGISTRATION	Vikas Arora	01-SEP-2021 11:45:12	
SUBMISSION ACCEPTED	ca643fb2-7c35-8131- 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	
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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	





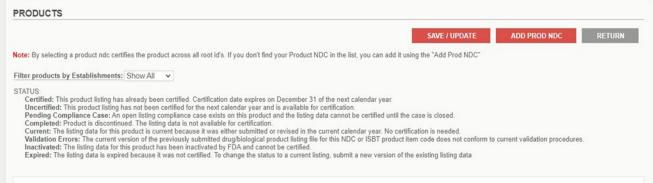
1

55555-777

55555-999

Wonderdrug

Wondercream



Q V Rows 15 V ACTIONS V												
•	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	DELETE				
0	55555-111	WonderPatch	-	26-MAR-22	PATCH	SALICYLIC ACID (40 1+	Uncertified	0.00				
0	55555-222	WonderGel	a)	26-MAR-22	GEL	SALICYLIC ACID (40 1+	Uncertified	(%)				
£	55555-333	Wonderdrug	2	26-MAR-22	TABLET	COAL TAR (200 mg)	Inactivated	120				

26-MAR-22

26-MAR-22

TABLET

CREAM

COAL TAR (2000 mg)

COAL TAR (5 g/100 g)+

1 - 5 of 5

Uncertified

Uncertified





### **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 <u>required</u> in order to certify a listing.
- Please keep your drug listings current!



# Thank you!

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