Annual Certification of Drug Product Listings

Regie Samuel
Technical Information Specialist
OC/OUDLC/DRLB
CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT
October 13, 2021

Who Must Certify and When?

Since the legal 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 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 1st – December 31st, 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.

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 1st 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)

https://direct.fda.gov

LIVE DEMO
on
CDER Direct

Home

SUBMISSIONS

(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
- Establishment Registration
- Product Listing and Certification

MANAGE ACCOUNT

- Edit User Profile
- Manage Users

COVID-19

(Not applicable to 503B outsourcing or compounding facilities)

To list Hand Sanitizers you first need to submit a Labeler Code Request and an Establishment Registration. When these have been completed you can then submit a Product Listing. Please view the user guides below for each submission type.

Labeler Code Request

Establishment Registration

Product Listing - Hand Sanitizer

ALL SUBMISSIONS

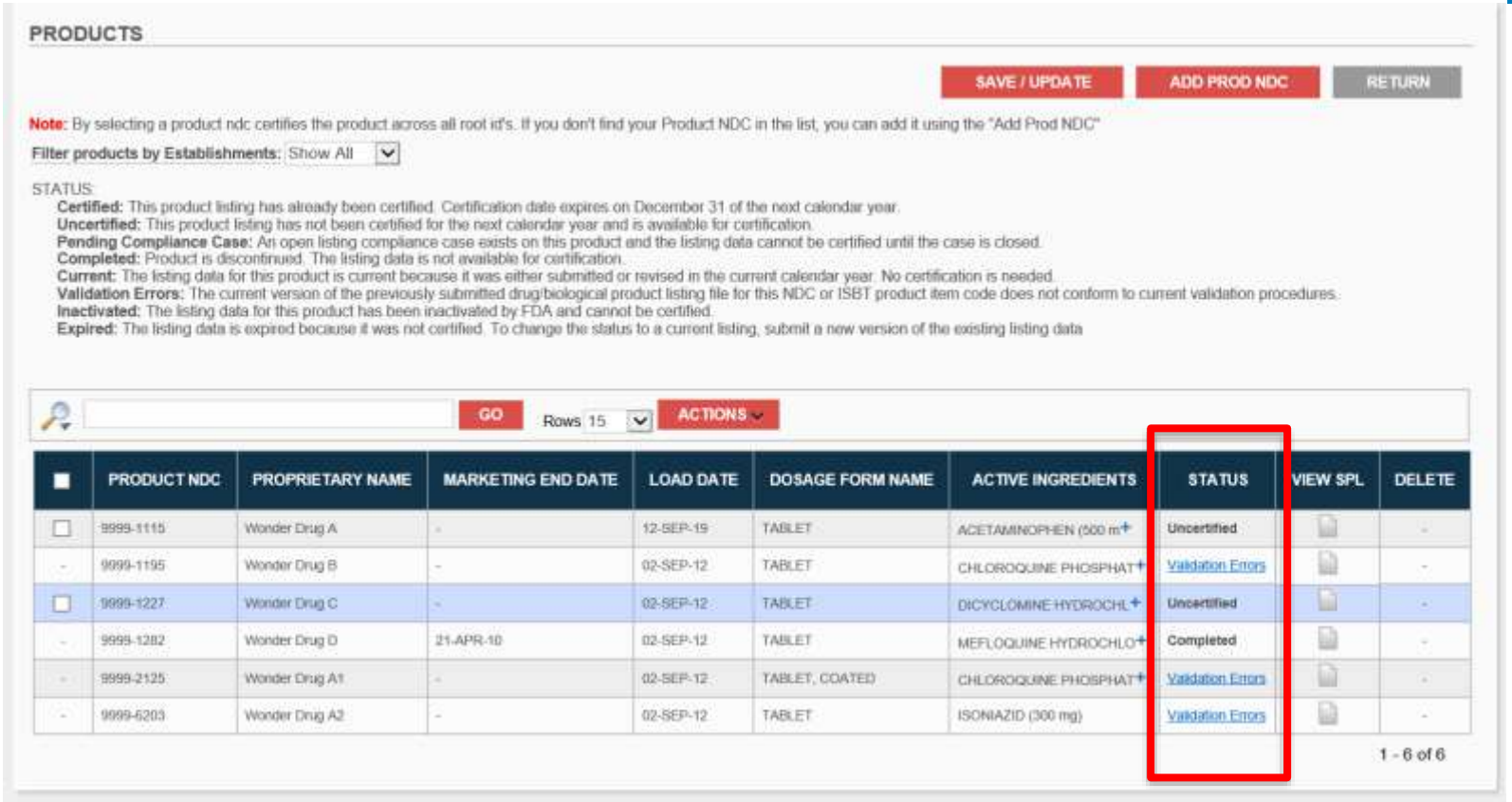
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov

GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
DRAFT	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	-	3	ESTABLISHMENT REGISTRATION	Regie Samuel	03-OCT-2021 17:23:41	
DRAFT	cd769994-0b9f-1223-e053-2995af0ab92e	cd769994-0ba0-1223-e053-2995af0ab92e	-	1	ESTABLISHMENT REGISTRATION	Regie Samuel	03-OCT-2021 12:52:22	

1 - 2

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 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	VIEW SPL	DELETE
☐	9999-1115	Wonder Drug A	-	12-SEP-19	TABLET	ACETAMINOPHEN (500 m+	Uncertified		-
-	9999-1195	Wonder Drug B	-	02-SEP-12	TABLET	CHLOROQUINE PHOSPHAT+	Validation Errors		-
☐	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+	Validation Errors		-
-	9999-6203	Wonder Drug A2	-	02-SEP-12	TABLET	ISONIAZID (300 mg)	Validation Errors		-

1 - 6 of 6

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