Listing Updates and Blanket “No Changes” Certification Demo

Yogesh Paruthi, PharmD
Consumer Safety Officer
Division of Labeling, Registration, and Unapproved Drugs
Office of Unapproved Drugs & Labeling Compliance
OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct – SBIA 2024 Workshop

Learning Objectives

- Describe drug listing update and listing certification requirements
- Describe what information must be submitted
- Explain who needs to update and certify

Drug Listing Updates Requirements

- Under 21 CFR 207.57(b)(1), each registrant must review and update their drug listing information no later than June and December of each year:
  - Any drug manufactured that was not previously listed
  - Any drug discontinued
  - Any previously discontinued drug which manufacturing has resumed
  - Any material change to previously submitted information

Drug Listing Updates Requirements

- Under 21 CFR 207.57(c), registrants are encouraged to update listing information at the time of any change affecting information previously submitted.
  - This will assist FDA in maintaining the most up-to-date information about drugs in U.S. commercial distribution

Listing Updates Live Demonstration

https://direct.fda.gov

FDA Direct
CDER Direct

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All Submissions > Drug Listing and Certification

ESTABLISHMENT REGISTRATION & DRUG LISTING
- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING
- Wholesale Drug Distributor and Third-Party Logistics Provider Reports

GENERIC DRUG SELF-IDENTIFICATION
- Generic Facility GDUFA Self-Identification

COSMETIC REGISTRATION AND LISTING
- Registration of Cosmetic Product Facility
- Cosmetic Product Listing

SELF HELP
- Structured Product Labeling Resources

DRUG LISTING AND CERTIFICATION

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

- Product listing that is newly listed or updated during the current calendar year is certified through December 31 of the following calendar year.
- Blanket No Changes Certification SPL can only be submitted from October 1 – December 31.
- Only a status of "Submission Accepted" indicates that a submission has successfully passed automated validation and been received by FDA.
- Products will appear on the National Drug Code (NDC) Directory only after the marketing start date has been reached. Please note that not all products are published on the NDC Directory as noted under "Important Considerations about the NDC Directory".

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 DATE	
DRAFT	20354ad9-a8b6-75c7-e063-6b94af0a5eb3	20354ad9-a8b7-75c7-e063-6b94af0a5eb3		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Yogesh Paruthi	27-AUG-2024 16:50:11	-
DRAFT	003dc6f7-7e22-eb65-e063-6a94af0ac1d8	003dc6f7-7e23-eb65-e063-6a94af0ac1d8		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Yogesh Paruthi	27-AUG-2024 16:17:54	-
SUBMISSION ACCEPTED	8ea68046-8b6a-4dd0-9803-35f5ac63c8af	20aff88b-aa74-484c-e063-6b94af0a6e10	cd2580913764.421695873O@direct	4	HUMAN OTC DRUG LABEL	LIQUID HAND SANITIZER	DETAILS	Yogesh Paruthi	27-AUG-2024 15:16:03	-
DRAFT	01561010-8f0e-b490-e063-6b94af0a9495	01561010-8f0f-b490-e063-6b94af0a9495		1	HUMAN PRESCRIPTION DRUG LABEL	-	DETAILS	Yogesh Paruthi	27-AUG-2024 15:15:07	-
SUBMISSION ACCEPTED	8ea68046-8b6a-4dd0-9803-35f5ac63c8af	ffbee913-4544-78b8-e053-6a94af0afb72	cd1257869403.5601439782@direct	3	HUMAN OTC DRUG LABEL	LIQUID HAND SANITIZER	DETAILS	Yogesh Paruthi	12-SEP-2023 13:55:09	-

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Challenge Question # 1

How often must a registrant review and update their drug listing information?

a. Once a year
b. Every month
c. As soon as possible
d. June and December each year

Listing Certification Requirements

- Under 21 CFR 207.57(b)(2), drugs not initially listed or updated during the calendar year must be updated or certified that the data has not changed since the last update.
- Blanket No Change SPL:
  - Available October 1 – December 31, during the annual period of registration renewal and drug listing certification window

Listing Certification Requirements

- Outside the annual certification window, an update or revision of the drug listing SPL submission for each NDC is required for certification
- Drug listings not certified will be considered expired in January and may be inactivated and removed from databases
- An inactivated listing record DOES NOT cover delisting requirements

Blanket “No Changes” Certification Demonstration

https://direct.fda.gov

FDA **FDA** *Direct*, **CDER** *Direct*

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DRAFT	20354ad9-a8b6-75c7-e063-6b94af0a5eb3	20354ad9-a8b7-75c7-e063-6b94af0a5eb3		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Yogesh Paruthi	28-AUG-2024 10:00:42	-
AWAITING ACCEPTANCE	8ea68046-8b6a-4dd0-9803-35f5ac63c8af	20ad8b94-3178-966c-e063-6b94af0af89f	cd7465093812.3862495701@direct	5	HUMAN OTC DRUG LABEL	LIQUID HAND SANITIZER	DETAILS	Yogesh Paruthi	27-AUG-2024 17:21:16	-
DRAFT	003dc6f7-7e22-eb65-e063-6a94af0ac1d8	003dc6f7-7e23-eb65-e063-6a94af0ac1d8		1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	-	-	Yogesh Paruthi	27-AUG-2024 16:17:54	-
SUBMISSION ACCEPTED	8ea68046-8b6a-4dd0-9803-35f5ac63c8af	20aff88b-aa74-484c-e063-6b94af0a6e10	cd2580913764.4216958730@direct	4	HUMAN OTC DRUG LABEL	LIQUID HAND SANITIZER	DETAILS	Yogesh Paruthi	27-AUG-2024 15:16:03	-
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Challenge Question # 2

When can a Blanket “No Changes” Certification SPL be submitted?

a. Once a year
b. October 1 – December 31
c. At any point in the year
d. June and December each year

Challenge Question # 3

To delist your product, you should change marketing status from active to complete.

a. True

b. False

Resources

- https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls

Summary

- Update your drug listing no later than June and December each year
- Blanket “No Changes” Certifications window available annually from October 1 – December 31
- Delist your product if its no longer in U.S. commercial distribution. An inactivated listing data is not in compliance, even if the drug is discontinued.

Questions?

Division of Labeling, Registration and Unapproved Drugs, OUDLC
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