NDC Reservation

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Electronic Drug Registration and Listing Using CDER DIRECT

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Overview

- Benefits of NDC Reservation
- Who should reserve an NDC
- When to Reserve
- How to reserve an NDC (National Drug Code) in CDER Direct

Benefits

- Preparation for a product launch
- Once accepted, the proposed NDC is reserved for 2 years
- Prevention of duplicate and formatting issues before drug listing
- CMOs can reserve an NDC using a PLD’s labeler code

Who Should Reserve?

- Preparation for a product launch – Pre-printing labels
- CMOs responsible for the PLD's drug listing
- Reservations should be used if the company is uncertain of marketing status, unsure of the product's final approved formulation, and the final physical characteristics (color, shape, imprint etc.)

When to Reserve

- If the NDC appears on the label:
- Prior to final labeling approval and printing
- The reservation is not required prior to the actual listing submission
- Do not reserve an NDC if you do not intend to start the commercial distribution within 2 years.

Dos and Don’ts

- The labeler code included in the reservation SPL, should be a labeler code that is electronically assigned by and submitted to FDA.
- Required data elements for NDC Reservation:
  - Labeler Name, Labeler DUNS, NDC Product Code, Non-Proprietary Name, Dosage Form, Marketing Status, Reserved Until Date, and 1 Active Ingredient.

Dos and Don’ts

- NDCs under the same labeler code can be reserved on the same NDC Reservation SPL
- Once accepted, the proposed NDC is reserved
- NDC is reserved at the product level:
  - Labeler Code and Product Code
  - No packaging information needed
- No additional data is “required” for NDC Reservation

Dos and Don’ts

- Marketing Status for all reserved NDC is “New” or “Reserved”
- To convert an NDC Reservation SPL to a Listing SPL, the Marketing Status must be switched from “Reserved” to “Active”
- A Reserved NDC that is no longer needed can be canceled
- To cancel an NDC Reservation, change the Marketing Status from “Reserved” to “Cancel”

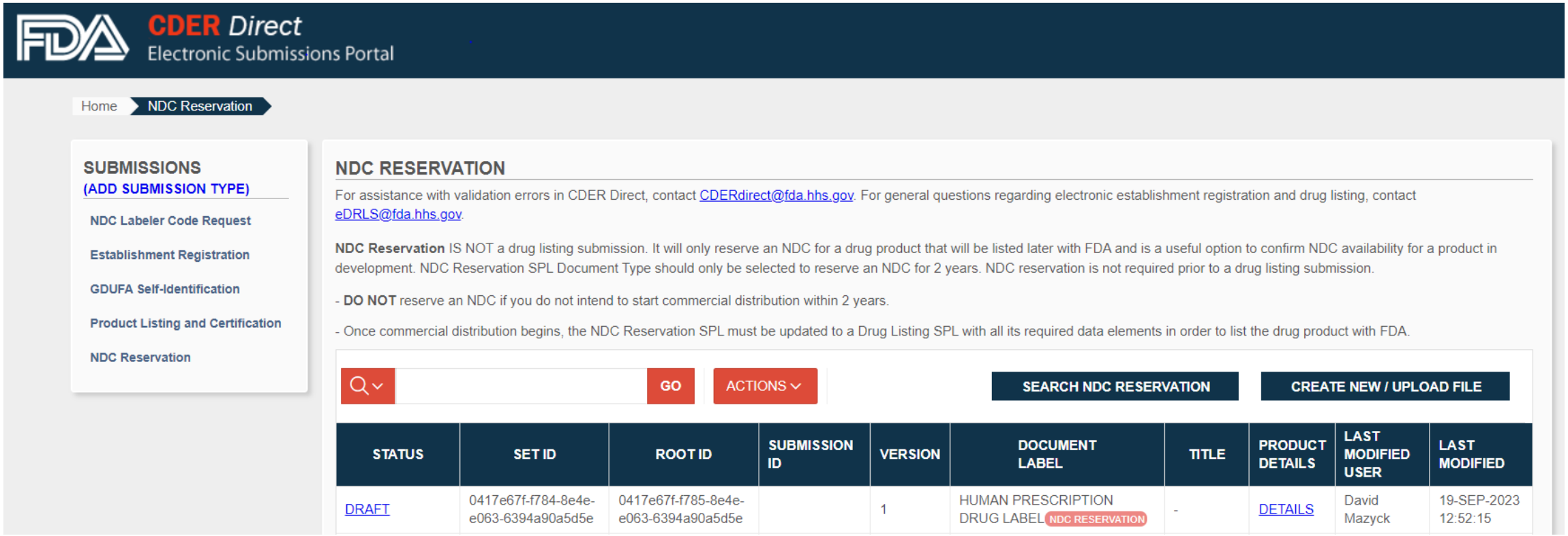
Dos and Don’ts

- Cancelling an NDC Reservation is effective on day of submission
- A reserved NDC, will not be available for reservation or listing of other products.
- An NDC Reservation cannot be submitted for an NDC which has already been used.
- A previously reserved NDC becomes available once its reservation is canceled

Key Facts

- NDC Reservation is not drug listing
- Limited data elements required
- Data will not be published until properly listed
- Effective date is the Submission date
- Reserved until date can be up to 2 years after the Effective Date

NDC Reservation



Home > NDC Reservation > Products

SUBMIT SPL | SAVE AS DRAFT | SAVE AND VALIDATE | DELETE | << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Products submission form. Red asterisk indicate required fields.

Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.

HEADER DETAILS

Document Type: * HUMAN PRESCRIPTION DRUG LABEL NDC RESERVATION

Version Number: * 1

Set ID: * 0417e67f-f784-8e4e-e063-6394a90a5d5e Generate New

Effective Date: * 07-14-2023

Root ID: * 0417e67f-f785-8e4e-e063-6394a90a5d5e Generate New

Title

LABELER DETAILS

Labeler Name: * Pharm1906

Labeler DUNS: * 12345678

REGISTRANT DETAILS

Registrant Name:

Registrant DUNS:

Confidential

ESTABLISHMENTS

ADD ESTABLISHMENT

None

PRODUCTS

ADD PRODUCT

GO

ACTIONS

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	CLONE PRODUCT
	54321-001	-	CAPSULE	

PRODUCT DATA ELEMENTS

NDC Product Code: * 54321-001

Proprietary Name:

Non Proprietary Name: * CARCAS1

Suffix:

DEA Schedule: -- Select DEA Schedule --

Dosage Form: * CAPSULE

Route of Administration:

AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS

ORAL

Source NDC:

MARKETING DETAILS

Marketing Status: * RESERVE

Reserved Until Date: * 07-14-2025

Marketing Category: -Select Marketing Category-

Application Number/ Regulatory Citation:

SAVE INGREDIENT | << RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Denominator Strength: *

Unit of Measure: * -- Select One --

Type: * -- Select One --

Ingredient UNII - Name: *

Strength: *

Unit Of Measure: * -- Select One --

Active Moiety: *

ADD ACTIVE MOIETY

Reference Ingredient: *

Challenge Questions

- NDC reservation is required to facilitate the listing submission. T/ F
- The reservation date may be up to 2 years after the effective date. T/F
- Reservation data is published on the NDC directory. T/F

Contact Us:

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