U.S. FOOD & DRUG ADMINISTRATION

NDC Reservation

David E Mazyck
Consumer Safety Officer
Drug Registration and Listing Staff
FDA/CDER/Office of Compliance
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
- Demo - 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.

Key Facts

- 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.

Key Facts

- 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

Key Facts I

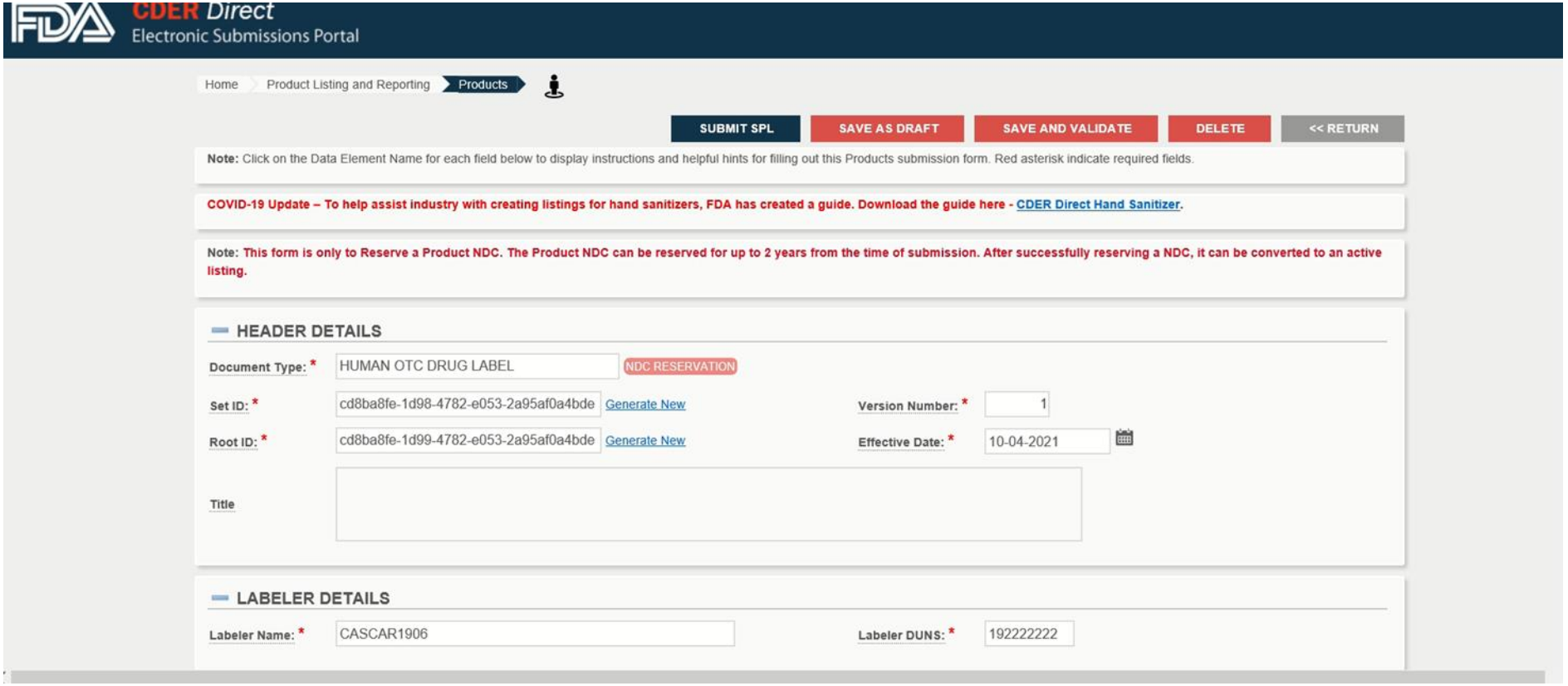
- Marketing Status for all reserved NDC is “New” or “Reserved”
- To convert an NDC Reservation SPL to a Listing SPL, the Marketing Status must be switched from “Reserved” to “Active”
- A Reserved NDC that is no longer needed can be canceled
- To cancel an NDC Reservation, change the Marketing Status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

Key Facts II

- 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 III

- 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


CDER Direct
Electronic Submissions Portal
Home
Product Listing and Reporting
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.
COVID-19 Update – To help assist industry with creating listings for hand sanitizers, FDA has created a guide. Download the guide here - CDER Direct Hand Sanitizer.
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 OTC DRUG LABEL
NDC RESERVATION
Set ID: *
cd8ba8fe-1d98-4782-e053-2a95af0a4bde
Generate New
Version Number: *
1
Root ID: *
cd8ba8fe-1d99-4782-e053-2a95af0a4bde
Generate New
Effective Date: *
10-04-2021
Title
LABELER DETAILS
Labeler Name: *
CASCAR1906
Labeler DUNS: *
192222222

LABELER DETAILS

Labeler Name: * CASCAR1906

Labeler DUNS: * 192222222

REGISTRANT DETAILS

Registrant Name: CASCAR1906

Registrant DUNS: 192222222

☐ Confidential

ESTABLISHMENTS

ADD ESTABLISHMENT

None

PRODUCTS

ADD PRODUCT

GO ACTIONS

None.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