

NDC Reservation

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Overview



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

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.



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



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- Data will not be published until properly listed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 > Product Listing and Reporting

SUBMISSIONS

Product Listing and Certification

PRODUCT LISTING AND REPORTING



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	
DRAFT	94566c0d-52df-60c7-e053-2995af0a5b4e	94566c0d-52e0-60c7-e053-2995af0a5b4e	-	1	HUMAN PRESCRIPTION DRUG LABEL NDC RESERVATION		DETAILS	David Mazyck	10-OCT-2019 09:21:26	-

1 - 1

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 RESERVATIONSet ID: * 94566c0d-52df-60c7-e053-2995af0a5b4e [Generate New](#)

Version Number: * 1

Root ID: * 94566c0d-52e0-60c7-e053-2995af0a5b4e [Generate New](#)Effective Date: * 10-07-2019 UTC

Title

— LABELER DETAILS

Labeler Name: * Pharma1906

Labeler DUNS: * 123456789

— REGISTRANT DETAILS

Registrant Name:

Registrant DUNS:

☐ Confidential

— ESTABLISHMENTS

ADD ESTABLISHMENT

None

— PRODUCTS

ADD PRODUCT



GO

ACTIONS

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SELECT

PRODUCT NDC

PROPRIETARY NAME

DOSAGE FORM



CLONE PRODUCT

FDA

PRODUCT DATA ELEMENTS

NDC Product Code: *	<input type="text" value="54321-000"/>	Proprietary Name:	<input type="text" value="Drug 1"/>	Suffix:	<input type="text"/>
Non Proprietary Name: *	<input type="text" value="Drug 1"/>	DEA Schedule:	<input type="text" value="-Select DEA Schedule-"/> ▼		
Dosage Form: *	<input type="text" value="CAPSULE"/> ▼				
Route of Administration:	<div><div><div>AURICULAR (OTIC) BUCCAL CONJUNCTIVAL CUTANEOUS DENTAL ELECTRO-OSMOSIS</div><div><div>↕</div><div>↗</div><div>↘</div><div>↕</div></div><div><div>↕</div><div>↗</div><div>↘</div><div>↕</div></div></div><div><div>↕</div><div>↗</div><div>↘</div><div>↕</div></div><div><div>↕</div><div>↗</div><div>↘</div><div>↕</div></div></div>				
Source NDC:	<input type="text"/>				

MARKETING DETAILS

Marketing Status: *	<input type="text" value="RESERVE"/> ▼	
Reserved Until Date: *	<input type="text" value="10-04-2021"/>	 
Marketing Category:	<input type="text" value="OTC monograph final"/> ▼	
Application Number/ Regulatory Citation:	<input type="text"/>	

INGREDIENTS

[ADD INGREDIENT](#)

Note: * At least one active ingredient is required

NDC Reservation



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: *

Type: *

Ingredient UNII - Name: *

Strength: *

Unit Of Measure: *

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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