

NDC Reservation

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Overview

- Who Should Reserve
- When to Reserve
- Benefits
- Live Demo
- Tips for NDC Reservation
- Questions

Who Should Reserve?

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

When to Reserve?

- If NDC included on the label:
- Prior to final labeling approval
- Prior to labeling printing
- Do not reserve an NDC if you do not intend to start commercial distribution in over two years

Benefits?

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

Tips Regarding Reservation

- The labeler code included in the reservation SPL, should be a labeler code that is electronically assigned by and submitted to FDA.
- NDC Reservation for Kits is currently not available, this feature is anticipated to be available in near future.
- 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.

LIVE DEMO

on

NDC Reservation

Tips for NDC Reservation

- 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

Tips -- Continued

- 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”

Tips -- Continued

- 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 used.
- A previously reserved NDC becomes available once its reservation is canceled.

Tips -- Continued

- A listing SPL with future “Marketing Start Date” was occasionally used to “Reserve” NDCs:
 - If data elements change, the listing revision can be rejected
 - Manual override must be approved by CDER and done by SPL Coordinator -- Timely process
 - Launch plans can change or get cancelled, but drug gets listed, if listing SPL is not updated

Tips -- Continued

- A “cancelled” NDC can be assigned to other products or used by other CMOs
- Complete listing data elements (versus minimum for reserving)

Resources

- Link to DRLS Webpage and toolkit

<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm>

- National Drug Code Directory

<https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>

Questions?

Contact Us:

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