NDC Reservation

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Objectives

- Describe the required elements for the NDC Reservation file.
- Provide details on the timeframe for submitting the file.
- Explain the importance of the use of the NDC Reservation.

Benefits

- Preparation for a product launch
- The proposed NDC is reserved for 2 years once accepted
- Prevention of duplicated 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- Printing labels
- CMOs responsible for the PLD's drug listing
- Reservations should be used if the company is uncertain of the marketing status, unsure of the product's final approved formulation, and the final physical characteristics (imprint information, color shape 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 reverse 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

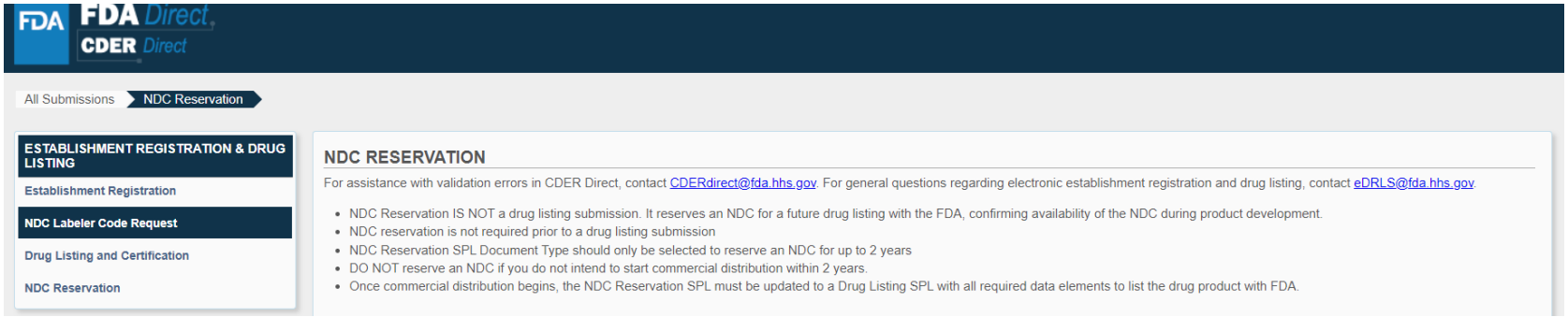
Key Facts

- 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

- 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

CDER Direct: NDC Reservation



Challenge Question #1

Which of the following data elements can be excluded from the NDC reservation file?

A. Labeler Name

B. Labeler DUNS

C. Package Code

D. Active ingredient

Challenge Question #2

- NDC reservation is required to facilitate the listing submission. T/ F

Question # 3

- Reservation data is published on the NDC directory. T/F

Summary

- NDC Reservation SPL Document Type should only be selected to reserve an NDC for up to 2 years.
- The NDC reservation is not a complete drug listing submission.

Questions?

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