

NDC Assignment to Drugs

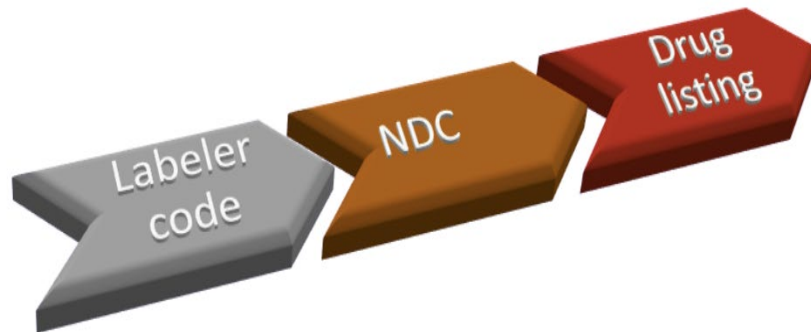
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Learning Objectives

- Determine how NDCs are assigned
- Determine what changes require a new NDC
- Describe products that require an NDC
- Describe products that should not use an NDC





Where's NDC?



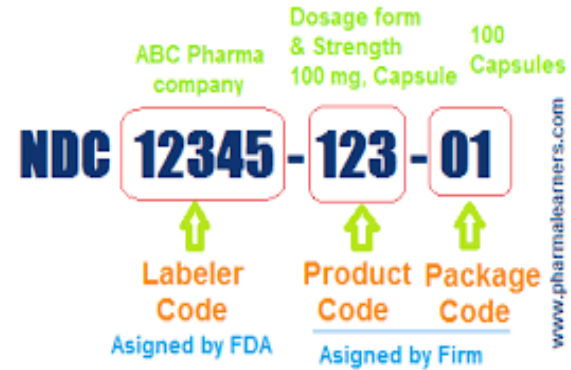


3 Segments of NDC

- Labeler Code
- Product Code
- Package Code
- NDC number can be assigned using following configurations:

4-4-2, 5-3-2, 5-4-1

Example of NDC



How are NDCs Assigned?



- Registrant proposes an NDC for a drug when drug listing is submitted
- NDC assignment is a separate process from the drug approval process
- Verification of NDC assignment is not typically part of the review and approval process
- The labeler can reserve an NDC



What changes require a new NDC?

- A new Product Code is required (21 CFR 207.35) when there is a change to following information:
 - Drug's established name or proprietary name
 - API or the strength of any API
 - Dosage form
 - A change in the drug's status
 - A change in the drug's intended use between human and animal
 - A change in drug's physical characteristics

What changes require a new NDC?



- With respect to the Package Code
 - Different package sizes and types cannot share the same package code
 - Multi-dose package drugs that contain the same concentration of active ingredient
 - Different packaging sizes
 - Packaged in different container materials

Products that require an NDC



- Drugs that are required to be listed under section 510 of the FD&C Act
 - All human prescription and nonprescription drugs
 - Biological products
 - Combination products that include either a drug or biological product constituent part
 - Drug samples

Products that should NOT use an NDC

- Medical Devices
- Medical Foods
- Dietary Supplements
- Cosmetics



NDC and Misbranding



- 21 CFR 207.77(b)
 - Any representation that creates the impression that a drug is approved or is legally marketable (i.e. assigned or display an NDC) is misleading and constitutes misbranding

Test Your Knowledge



A new product code is required when there is a change in route of administration.

- A. True
- B. False

Test Your Knowledge



1. Which of the following may not use an NDC?
 - A. Medical devices
 - B. Unapproved drug
 - C. Prescription drug
 - D. OTC product

