The National Drug Code (NDC)
Rules for Assigning and Changing NDCs

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Where’s NDC?
Agenda

• Introduction on the National Drug Code (NDC)
• Misconceptions of NDC
• Assignment of a new NDC
  – When to assign a new NDC and which segment to change
• Future of NDC
• Q&A Session
What is National Drug Code (NDC)?

• A unique **10-digit**, 3-segment number.
• Universal product identifier for drugs.
• Should not be assigned to non-drug products.
• Submission of NDC is required for drug listing.
• Assignment of NDC ≠ Approval
Timeline of NDC

1969
NDC voluntary reporting

1974
The Uniform Grocery Code Council (UGCC) introduced 12 digit UPC and barcodes

1972
Drug Listing Act of 1972
Mandatory inclusion of NDC
New NDC format 4-4-2

1986
HIPAA
Effective October 16, 2003
11 digit NDC format for all HIPAA transactions

1990
OBRA 90
Required to bill for drugs with NDCs - utilization review to collect rebates for Medicaid paid drugs

2004
Barcode Rule
Mandated linear barcode on all drug products starting in 2006

2009
FDA stopped accepting paper submissions for registration and listing on June 1

2011
New FDA NDC Directory started publishing on June 1

2013
Drug Supply Chain Security Act
2D matrix data barcode

2016
New registration and listing rule went into effect
Misconceptions regarding NDCs
10-digit vs. 11-digit

• Created an 11-digit derivative, where 0’s are added to achieve a fixed-length 5-4-2 configuration.

• Under HIPAA covered transaction, NDCs to be reported in an 11-digit format.

• Some govt. agencies and private payers require the NDC in an 11-digit format.
Example of 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
Labeler Code

- First set of numbers identify the LABELER.
- Manufacturer, packager or distributor.
- This code is assigned by the FDA.
Product Code

- Second set of numbers identify the PRODUCT CODE.
- Specific strength
- Dosage form
- Formulation of a drug
- Proposed by the labeler.
Package Code

• Third set of numbers identify the PACKAGE CODE.

• Identifies the package types and sizes.

• Proposed by the labeler.
Changes require a new NDC

• A New Product Code is required when there is a change to following information:
  – Drug’s established name or proprietary name
  – API or the strength of any API
  – Dosage form
Changes require a new NDC Continued

– 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
  
  • Size, Shape, Color
  
  • Code imprint,
  
  • Flavor, scoring (if any)
When to assigned a new Package Code?

• When there is a change ONLY to the Package size or type
Future of NDC

• Currently, 5-digit labeler codes are being assigned by FDA.

• FDA anticipates that it will run out of 5-digit LCs in approximately 15 years.

• In 2018, the FDA conducted a public hearing

Download the New NDC Express Mobile Application!