

# **The National Drug Code (NDC)**

## **Rules for Assigning and Changing NDCs**

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Where's NDC?



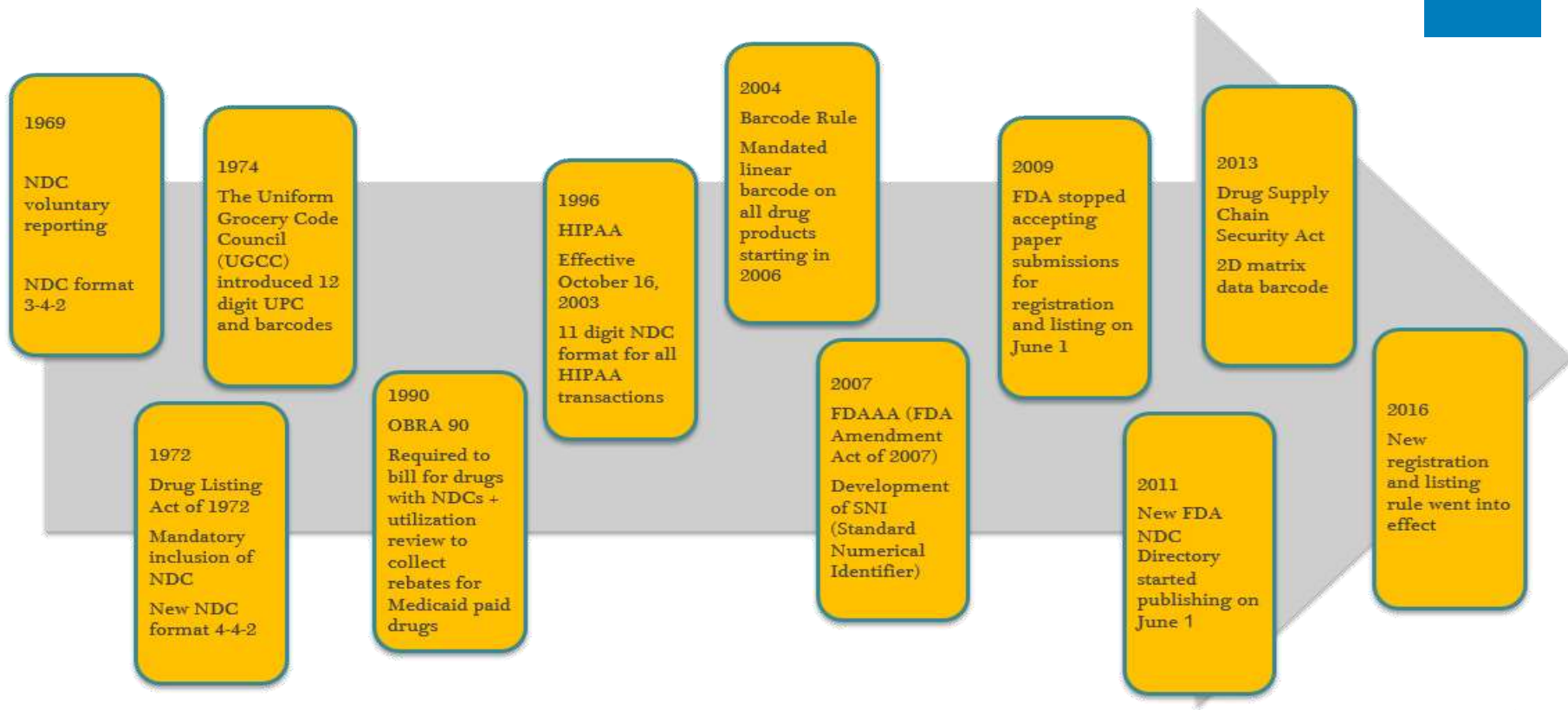
# *Agenda*

- 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  $\neq$  Approval

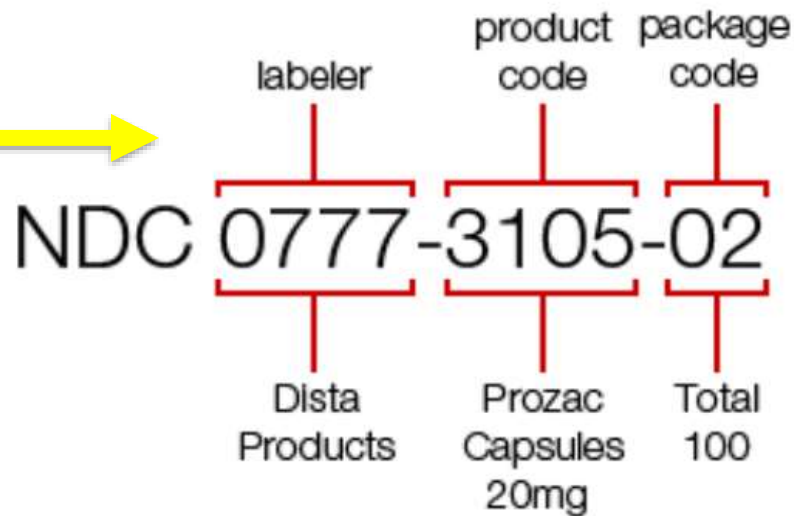


# *Misconceptions regarding NDCs*

## *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.



## ***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***

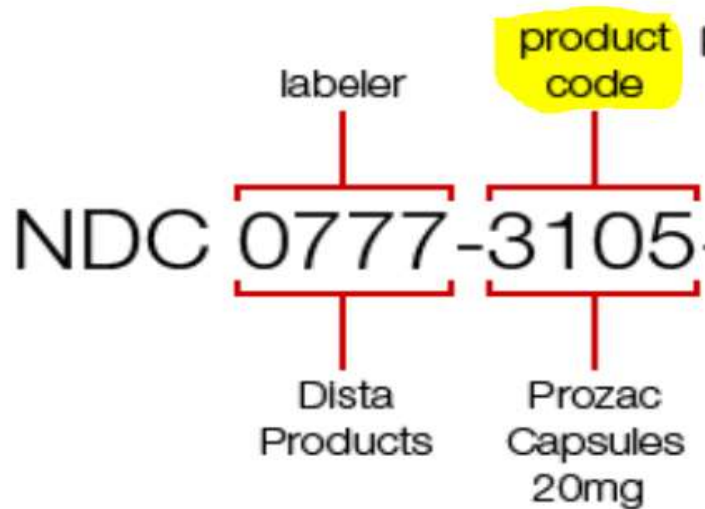
# *Labeler Code*

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



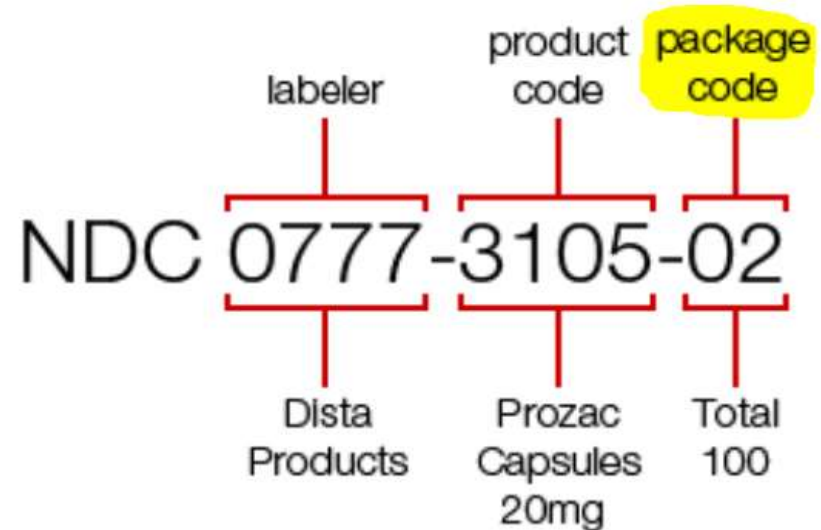
# *Product Code*

- 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*



- 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

Packaging	
#Item Code	Package Description
1 64679-735-01	30 in 1 BOTTLE; =
2 64679-735-02	100 in 1 BOTTLE; =
3 64679-735-03	500 in 1 BOTTLE; =



# *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
  - <https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-request-for-comments>

# ***Download the New NDC Express Mobile Application!***



