U.S. FOOD & DRUG ADMINISTRATION

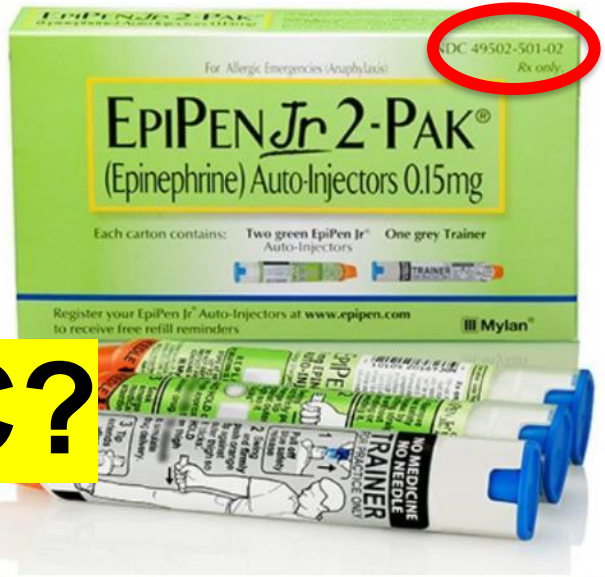
The National Drug Code (NDC)
Rules for Assigning and Changing NDCs

LCDR Soo Jin Park, Pharm.D., MS.
Regulatory Officer
Office: CDER/OC/OUDLC/DRLB


NDC 0071-0157-23
Rx only
90 Tablets
Lipitor
(atorvastatin calcium) tablets
10 mg*
40 mg*
Pfizer
Parke-Davis

Where's NDC?


AMOXICILLIN 500MG
Capsule
Generic for: Amoxil
Take one capsule by mouth three times daily for 10 days
qty: 30
refills: No
Dr. C Wilson
disp: TST
mfr:
(877)798-2743
6666056-1375
TARGET PHARMACY
900 Nicollet Mall
Minneapolis, MN 55403
PATIENT INFO CARD


NDC 49502-501-02
Rx only
For Allergic Emergencies (Anaphylaxis)
EpiPen Jr 2-Pak®
(Epinephrine) Auto-Injectors 0.15mg
Each carton contains: Two green EpiPen Jr® Auto-Injectors One grey Trainer
Register your EpiPen Jr® Auto-Injectors at www.epipen.com to receive free refill reminders
Mylan
NO MEDICINE NO NEEDLE TRAINER


NDC 59310-579-22
PROAIR® HFA
(albuterol sulfate)
Inhalation Aerosol
90 mcg per actuation
With Dose Counter
For Oral Inhalation with ProAir® HFA Actuator Only
Rx only
200 Metered Inhalations
8.5 g Net Contents
DPAB44A
04 2014

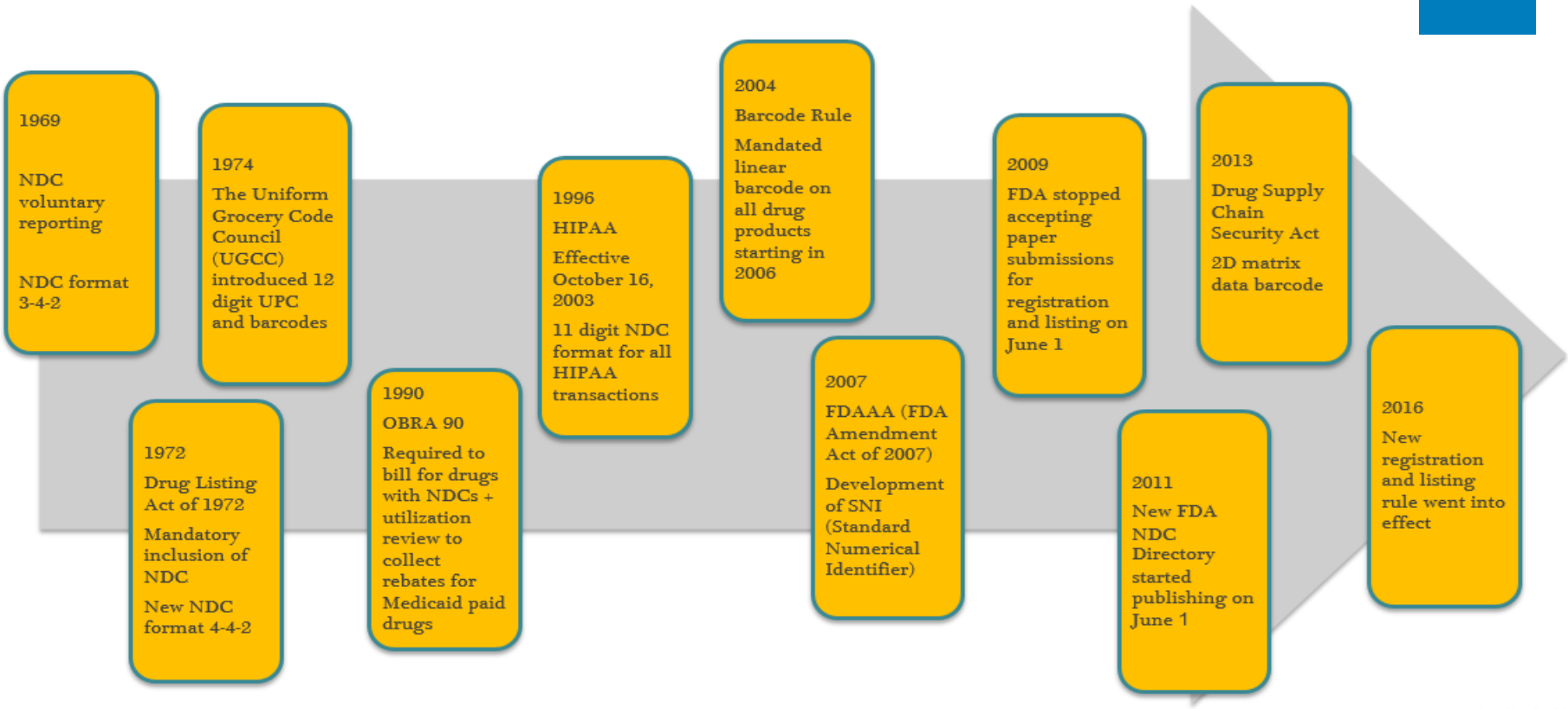

NDC 50580-409-80
Motrin® IB
LIQUID GELS
Ibuprofen Capsules, 200 mg
Pain Reliever / Fever Reducer (NSAID)
80 Liquid Filled Capsules
Actual Size

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)?

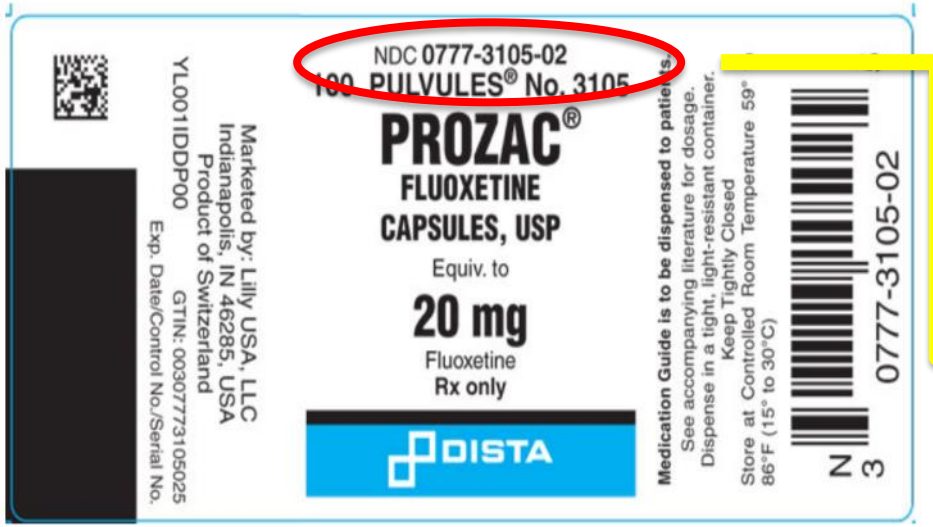
- A unique **10-digit**, 3-segment number.
- Universal product identifier for drugs.
- Should not be assigned to non-drug products.
- Submission of NDC is required for drug listing.
- Assignment of NDC $\neq$ Approval


1969
NDC voluntary reporting
NDC format 3-4-2
1972
Drug Listing Act of 1972
Mandatory inclusion of NDC
New NDC format 4-4-2
1974
The Uniform Grocery Code Council (UGCC) introduced 12 digit UPC and barcodes
1990
OBRA 90
Required to bill for drugs with NDCs + utilization review to collect rebates for Medicaid paid drugs
1996
HIPAA
Effective October 16, 2003
11 digit NDC format for all HIPAA transactions
2004
Barcode Rule
Mandated linear barcode on all drug products starting in 2006
2007
FDAAA (FDA Amendment Act of 2007)
Development of SNI (Standard Numerical Identifier)
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:

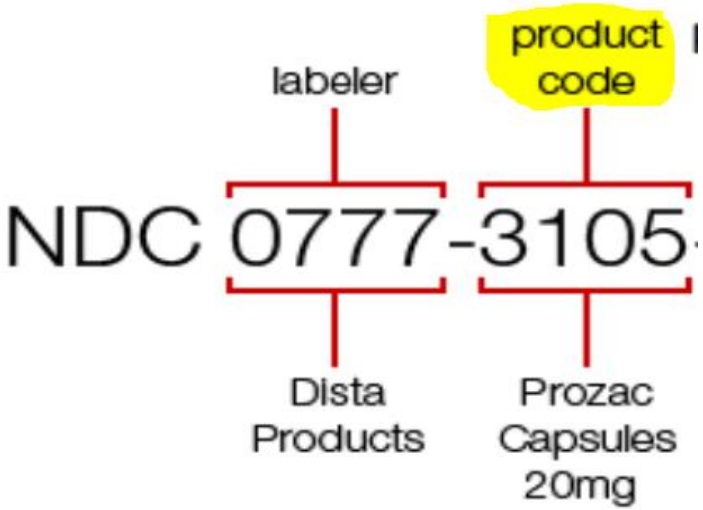
  4-4-2, 5-3-2, 5-4-1

Labeler Code

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

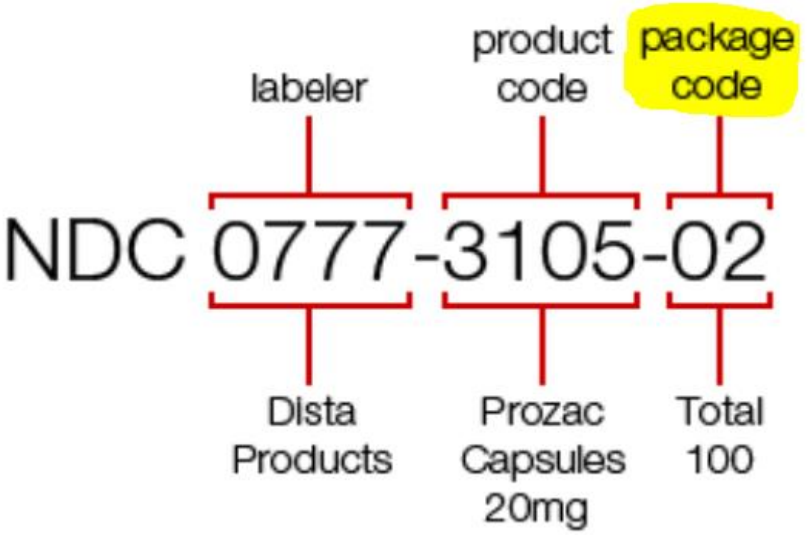
Product Code

- 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

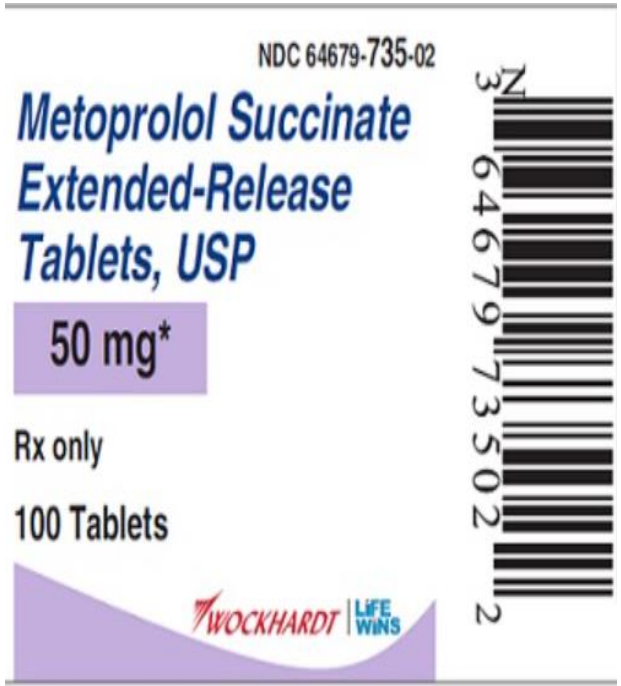
Changes require a new NDC Continued

- 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

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!