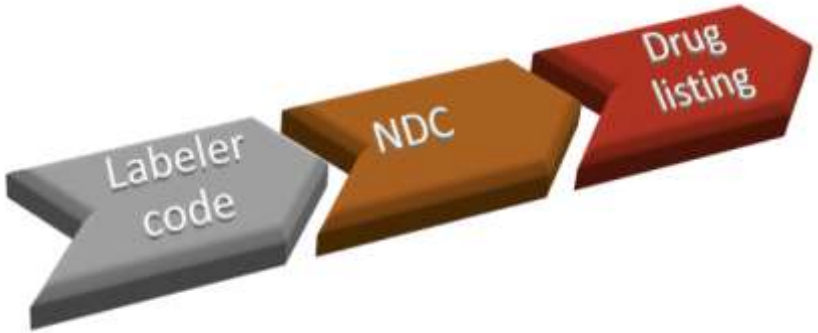
NDC Assignment to Drugs

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

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




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

Where's NDC?


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


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


NDC 49502-503-02
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
TRAINER
NO MEDICINE NO NEEDLE


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

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