NDC Assignment to Drugs

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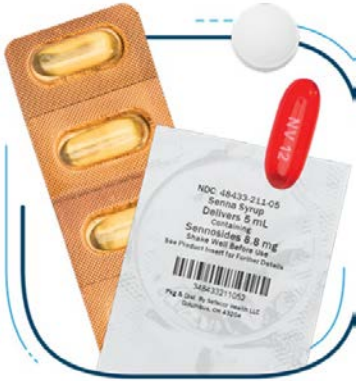
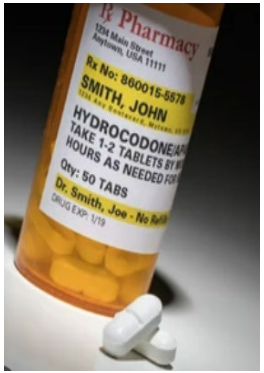
Learning Objectives

- Explain assignment of NDCs to drugs
- Describe the history of the NDC
- Describe NDC change requirements and restrictions


Rx only
NDC 55150-223-10
Methocarbamol
Injection, USP
1,000 mg per 10 mL
(100 mg / mL)
For Intravenous or
Intramuscular Injection
10 mL
Single Dose Vial
AUROMEDICS


NDC 48433-211-05
Senna Syrup
Delivers 5 mL
Sennosides 8.8 mg
Shake Well Before Use


Pharmacy
Rx No: 860015-5578
SMITH, JOHN
HYDROCODONE/AP
TAKE 1-2 TABLETS BY M
HOURS AS NEEDED FO
Qty: 50 TABS
Dr. Smith, Joe - No Refi
DRUG EXP: 1/19


See current Drug Facts
Treats FREQUENT Heartburn!
24 HR
Prilosec
omeprazole delayed-release tablets
20 mg / acid reducer
OTC®
14 TABLETS
One 14-day course of treatment
May take 1 to 4 days for full effect

What is NDC?

- NDC is a 10-digit identifier for drugs in the U.S.
- Consists of three segments
- Separated by hyphens
- Three Segments of the NDC
  - Labeler Code
  - Product Code
  - Package Code

How are NDCs assigned?

- Registrant proposes an NDC for a drug at the time of drug listing submission to FDA
- FDA assigns the proposed NDC
- NDCs are assigned to drugs only
  - No dietary supplement
  - No medical food
  - No medical device

History of NDC

- 1969- NDC voluntary reporting
- 1972- Drug Listing Act
- 1996- HIPPA Implementation
- 2016- New registration and listing rule went into effect

NDC Change Requirements

- Product code:
  - A change in drug's established name or proprietary name, if any
  - A change in active ingredient or strength
  - A change in dosage form
  - A change in drug status
  - A change in drug’s intended use
  - Any changes to the drug’s distinguishing characteristics
- Package code:
  - A change to a package size or type

NDC Restrictions

- NDC cannot be reused for a different drug, even after a product is disconnected
- Using NDC may cause the product to be misbranded
  - If used to represent a different drug
  - If used for non-drugs such as medical devices
- If a previously discontinued drug resumes marketing, the same NDC should be assigned

Legal Conformance

- Assignment of an NDC does not denote approval of the drug, nor does it mean that the drug may be legally marketed
- Any representation that creates the impression that a drug is approved or is legally marketable (21 CFR 207.77(a)(b))

NDC and Drug Labeling

- Printing NDC in a human readable format on drug container label is not required but strongly encouraged
  - Human prescription drugs
    - How Supplied/Storage and Handling section of the PI
    - NDCs for the units/package sizes
  - Human OTC drugs
    - Appropriate NDC on the container label and carton labeling

NDC and Drug Approval Process

- NDC is not part of labeling approval during drug approval process
- To remediate any issue:
  - Applicants can reserve an NDC
  - Direct any NDC questions to eDRLS@fda.hhs.gov

Co-Packaged Products

- When at least one drug is co-packaged with other drugs or non-drug articles
- NDC assignment:
  - NDC proposed to the co-packaged product should be different than NDC proposed for each drug part
  - Non-drug parts should not include an NDC

Multi-Level Packaged Drugs

- Multilevel package includes different levels of packaging for one drug
  - Carton containing a blister pack or multiple vials
  - Assign a different package code to each level of packaging
  - Packaging levels of a drug should be provided in drug listing SPL

Challenge Question # 1

Which of the following can be assigned an NDC?

A. OTC drug
B. Medical device
C. Human prescription drug
D. Dietary supplement
E. A & C

Challenge Question # 2

NDC proposed to the co-packaged product should be different than NDC proposed for each drug part

A. True

B. False

Summary

- NDC assignment is a separate process from the drug approval process
- Registrant proposes an NDC for a drug at the time of drug listing submission and FDA assigns the proposed NDC
- Printing NDC in a human readable format on drug container label is strongly encouraged
- Regardless of an NDC inclusion on a drug label or not, all drugs that must be listed with FDA, must be assigned an NDC

Questions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