U.S. FOOD & DRUG ADMINISTRATION

FDA DRUG TOPICS:

National Drug Code (NDC) for Health Care Providers

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Learning Objectives

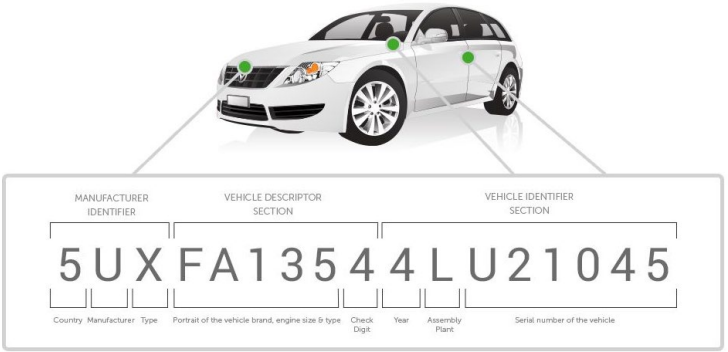
After completion of this activity, the participant will be able to:

- Review the history of NDC assignment to drugs in the United States.
- Identify the NDC on a drug label.
- Provide a list of NDC formats.
- Explain how to report incorrect data to FDA.
- Describe the future format of the NDC.

If yuo can raed tihs, yuo’re smtarer tahn a bracdoe scnaner!

Digital Identifiers

String of numeric or alpha-numeric characters which uniquely identify an object or entity within a digital system.

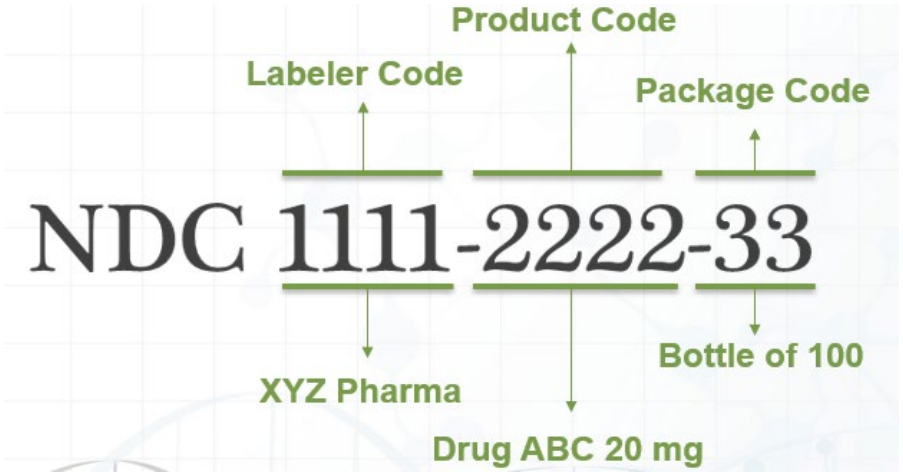


Identifiers for Drugs

- Global – International harmonization
  - IDMP (Identification of Medical Products -- ISO Standard)
  - GTIN (Global Trade Item Number -- Developed by GS1)
- Regional
  - Drug Identification Number (DIN) -- Canada
  - National Drug Code (NDC) -- USA
  - National Authorization Number -- EU

NDC

- Unique identifier for drugs in the U.S.
- Numeric characters
- 10 digits
- 3 segments, separated by hyphens
- NDC prefix



NDC Formats

- Official NDC current formats:
  - The 4-4-2 4444-4444-22
  - The 5-3-2 55555-333-22
  - The 5-4-1 55555-4444-1
- HIPAA (Health Insurance Portability and Accountability Act) Standard NDCs
  - The 5-4-2 55555-4444-22

Converting NDC Formats

- FDA NDC-10 to HIPAA standard NDC-11
  - 4444-4444-22 → 04444-4444-22
  - 55555-333-22 → 55555-0333-22
  - 55555-4444-1 → 55555-4444-01
- HIPAA standard NDC-11 to FDA NDC-10
  - More complicated in the absence of hyphens
  - 00220035101 → 0220-0351-01
    - 00220-351-01
    - 00220-0351-1

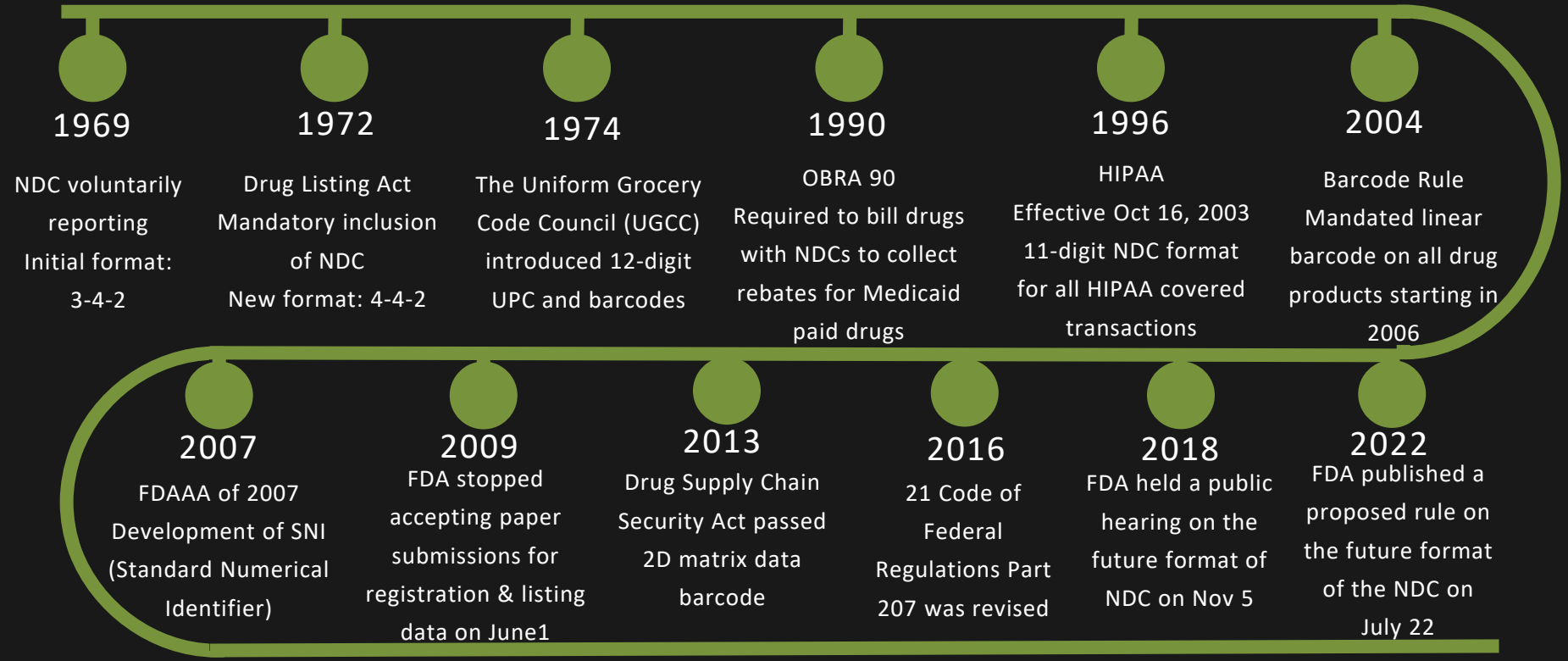
NDC Use

- Reimbursement
- Dispensing and administration
- Electronic Health Records and e-Prescribing
- Procurement
- Supply chain security
- Importation
- Recalls
- Safety and Adverse Event Reporting

Where Does the Drug Data Come From?

- Drug manufacturers are required to register their establishments and list all drugs they manufacture for U.S. commercial distribution
  - Section 510 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360
- Drug listing information is reported to FDA **using the NDC**
  - Drug Listing Act of 1972

A History Walk



Where is the NDC Found?

- Mostly on a drug label
  - Requested, but not required
- How Supplied Section of the Package Insert (PI)
- Within a barcode

NDC on Drug Label: Rx

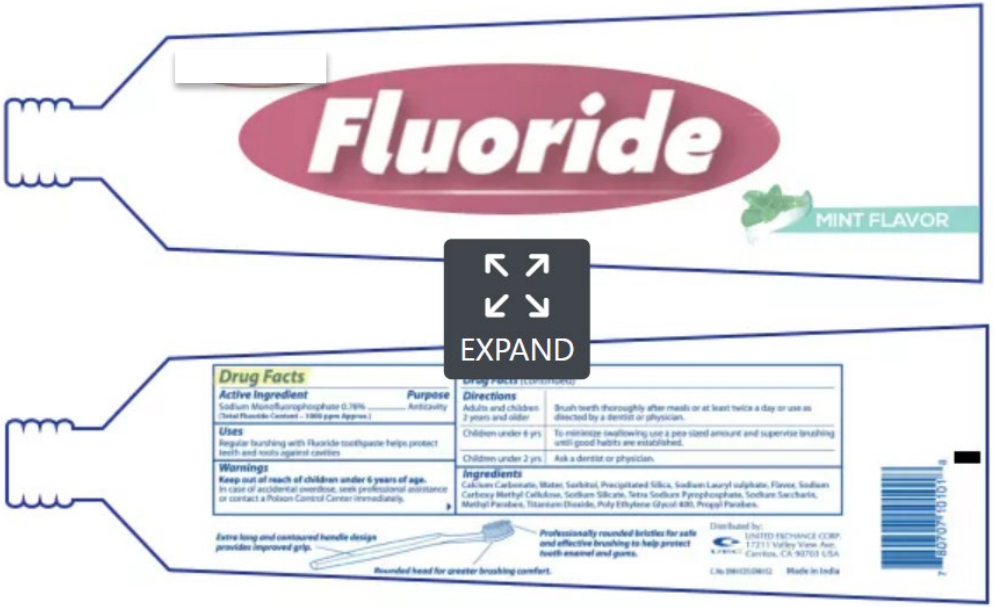
Data Matrix barcode (2D)

Linear barcode (1D)

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed

NDC on Drug Label: OTC



NDCs and Drugs

- NDC is required to be *assigned* to *all drugs* in U.S. commercial distribution, because *all drugs* in U.S. commercial distribution are required to be listed with FDA
  - Human or animal drugs
  - Rx or OTC drugs
  - Approved or unapproved drugs

NDCs and Non-drug Products

- NDC is the National *Drug* Code
  - It should not be assigned to products that are not drugs
- A product may be deemed to be misbranded if an NDC is used on non-drugs such as dietary supplements and medical devices

NDC Regulations

- 21 Code of Federal Regulations Part 207
  - FDA's acceptance of registration and listing information, inclusion of a drug in our database of drugs, or assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, 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 because it appears in our database of drugs, **has been assigned or displays an NDC**, or the establishment has been assigned an establishment registration number or Unique Facility Identifier is misleading and constitutes misbranding. *21 CFR 207.77(b)*

NDC Change Requirements

- 21 CFR 207.35: What changes require a new NDC?
  - Different product code: a change in established or proprietary name, active ingredient or its strength, dosage form, drug's status (Rx and OTC), intended use (animal and human), distinguishing characteristics
  - Different package code: different package size or type

Incorrect NDC Assignment

- Patient safety and medication errors
  - Incorrect assignment to different strengths of a drug
- Patient compliance and awareness
  - When physical characteristics of a drug change
- Drug identification
  - Poison Control Centers
- Incorrect billing and reimbursement issues
  - Incorrect package code assignment

NDC Directory

- Information is extracted from drug listing submissions to FDA
- Managed and published by FDA
- Includes finished and unfinished human drugs
- Does not include labeling
- Updated daily (weekdays)
- National Drug Code Directory | FDA

DailyMed

- Information is extracted from drug listing submissions to FDA
- Managed and published by NIH
- Includes human and animal drugs (and other products)
- Includes labeling
- Updated daily (weekdays)
- DailyMed

Incorrect Data

- FDA employs automated validations for drug listing submissions
- Some errors cannot be detected
- Contact FDA's Drug Registration and Listing Branch at eDRLS@fda.hhs.gov

Current NDC Situation

- FDA will run out of 5-digit labeler codes in 10-15 years
- Under current regulations, FDA will then start assigning 6-digit labeler codes
- Once implemented, a new NDC length (FDA NDC-11) and 2 new formats will be introduced:
  - The 6-3-2
  - The 6-4-1

Future of NDC

- FDA published a Federal Register Notice in August 2018
- Held public hearing on November 5, 2018
- Published a proposed rule on July 22, 2022
  - Proposed to standardize NDC to a 6-4-2 format
- FDA is currently working on finalizing the rule

Takeaway

- NDC is the major identifier for drugs in the U.S.
- NDC is part of drug listing submission to FDA
  - All drugs must be listed with FDA, and therefore, must be assigned an NDC
  - Drug listing or NDC assignment doesn't mean a product is a drug or it's legally marketed in the U.S.
- NDC is proposed at the time of drug listing by companies, and is assigned by FDA
- NDC may or may not appear on a drug label in a human readable format
- NDC format and length may change in the future

Resources

- National Drug Code Directory
- DailyMed
- Electronic Drug Registration and Listing System (eDRLS)
- Proposed Rule on Revising the National Drug Code Format

Questions?

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Closing Thought

Correct NDC assignment and use is essential to patient safety and healthcare administration. Follow FDA announcements to learn about its future format!


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