Format of the National Drug Code

FDA/OC/OUDLC/DRLB
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September 28, 2023

Objectives

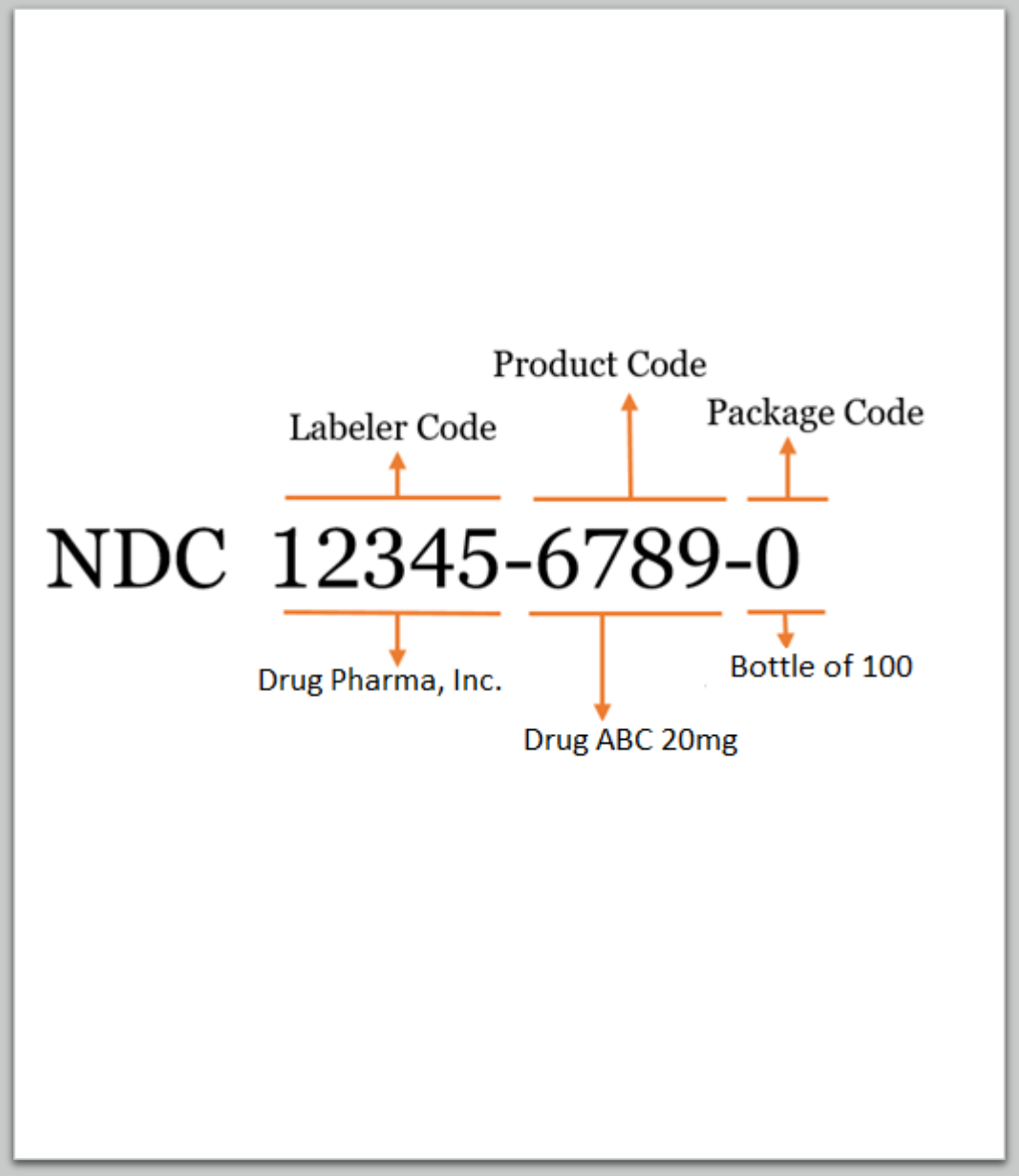
- Define the National Drug Code (NDC)
- Provide an overview of the proposed rule revising the NDC format
- Describe the proposed implementation timeline

What Is a National Drug Code (NDC)?

NDCs are unique identifiers for drugs in the United States. For most drugs, the NDC can be found on the labeling and can sometimes be part of the UPC.

NDC Segments and FDA-Assigned Formats Currently In Use

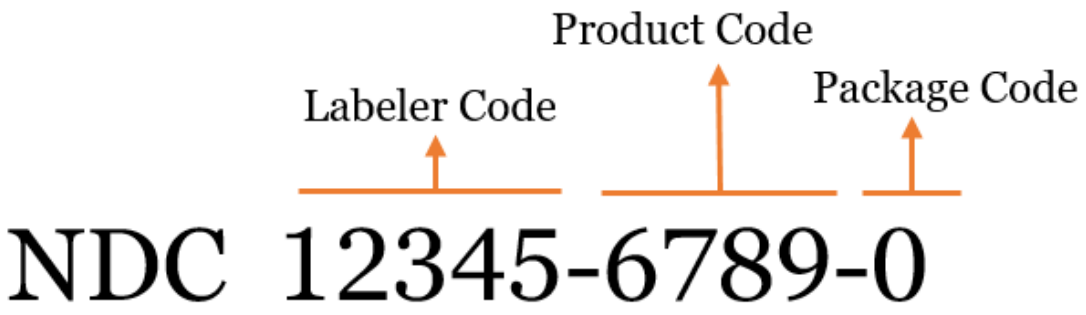
- 3 segments:
  - Labeler code
  - Product code
  - Package code
- 3 FDA-Assigned formats currently in use:
  - 4-4-2
  - 5-3-2
  - 5-4-1



The HIPAA Format

- Health Insurance Portability and Accountability Act
  - Adopted a uniform 11-digit NDC format that is required to be used when a HIPAA-covered transaction includes an NDC
  - This 11-digit format is standardized into a 5-4-2 format
  - An FDA assigned 10-digit NDC is converted to the HIPAA standardized 11-digit NDC format-by adding a leading zero to the applicable short segment

Current NDC Conversions



Current NDC Formats

	FDA 10-Digit NDC Formats XXXXX (FDA-assigned labeler code)		Examples of NDCs Converted into HIPAA 11-Digit Identifier Format (with zero added 0)	
		Segment Format	With Hyphens	Without Hyphens
Format 1	12345-6789-0	5-4-1	12345-6789-00	12345678900
Format 2	12345-678-90	5-3-2	12345-0678-90	12345067890
Format 3	1234-5678-90	4-4-2	01234-5678-90	01234567890

What Happens When FDA Runs Out of 5-digit Labeler Codes

- Under current regulations (21 CFR 207.33), once FDA runs out of 5-digit labeler codes, it will start assigning 6-digit labeler codes
- NDCs with 6-digit labeler codes would be 11-digits and would be required to be in one of the following 2 new formats:
  - 6-3-2
  - 6-4-1

Why Issue a Proposed Rule Now?

- The proposed rule is intended to minimize the impact of the transition to 6-digit labeler codes
- Under existing regulations, moving to 6-digit labeler codes will expand NDCs to 11-digits, and allow for 2 additional NDC formats
- FDA has about 10-15 years of available 5-digit labeler codes
- The timing uncertainty would increase impact

Emerging NDC Situation

Future Scenarios

FDA 11-Digit NDC Formats

Without any changes to the existing rule, there would be two additional formats created when 6-digit labeler codes are assigned.

		Segment Format
Format 4	123456-7890-1	6-4-1
Format 5	123456-789-01	6-3-2

- Without a change, there would be five NDC formats, 3 in 10-digits and 2 in 11-digits
- An FDA-assigned 11-digit NDC may cause confusion with HIPPA converted, 11-digit NDCs
- The healthcare system and payors currently convert 10-digit NDCs to 11-digit NDCs, which increases healthcare costs and may be a factor in medication errors

Possible Scenario if the Proposed Rule Is Not Adopted

		Segment Format	With Hyphens	Without Hyphens
Drug A (Format 1)	12345-6789-1	5-4-1 *(10 digits)*	12345-6789-01	12345678901
Drug B (Format 5)	123456-789-01	6-3-2 *(11 digits)*	123456-789-01	12345678901

Two distinct FDA-assigned NDCs for different drug products could result in the same HIPAA 11-digit identifier when hyphens are not used.

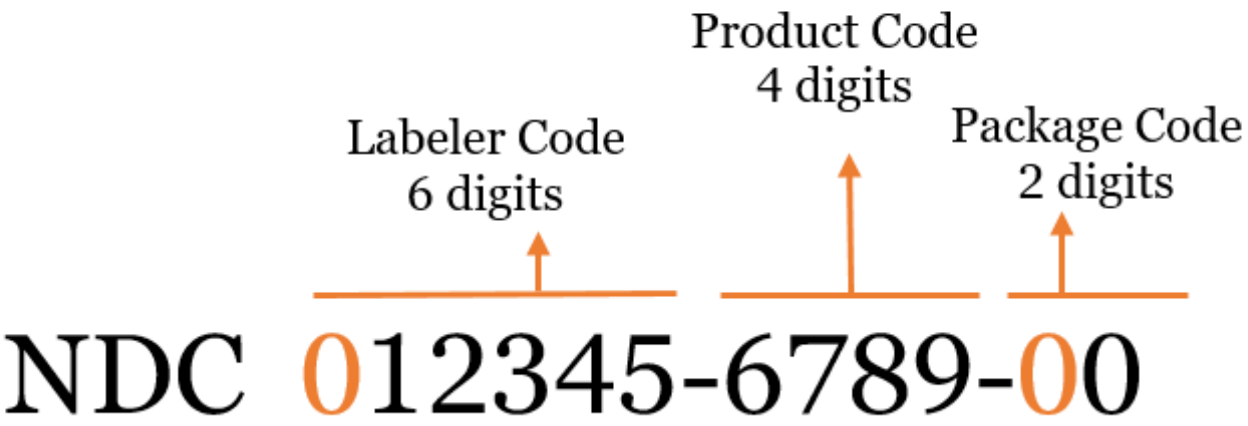
Who would be impacted by the NDC change?

- Human and animal drug manufacturers and distributors
- Insurers/payors
- Drug databanks
- Pharmacies
- Hospitals, clinics, labs, healthcare practitioners
- Nursing care facilities
- Electronic health record vendors
- Drug importers
- Federal agencies using the NDC
- State and local governments
- Various supply chain stakeholders

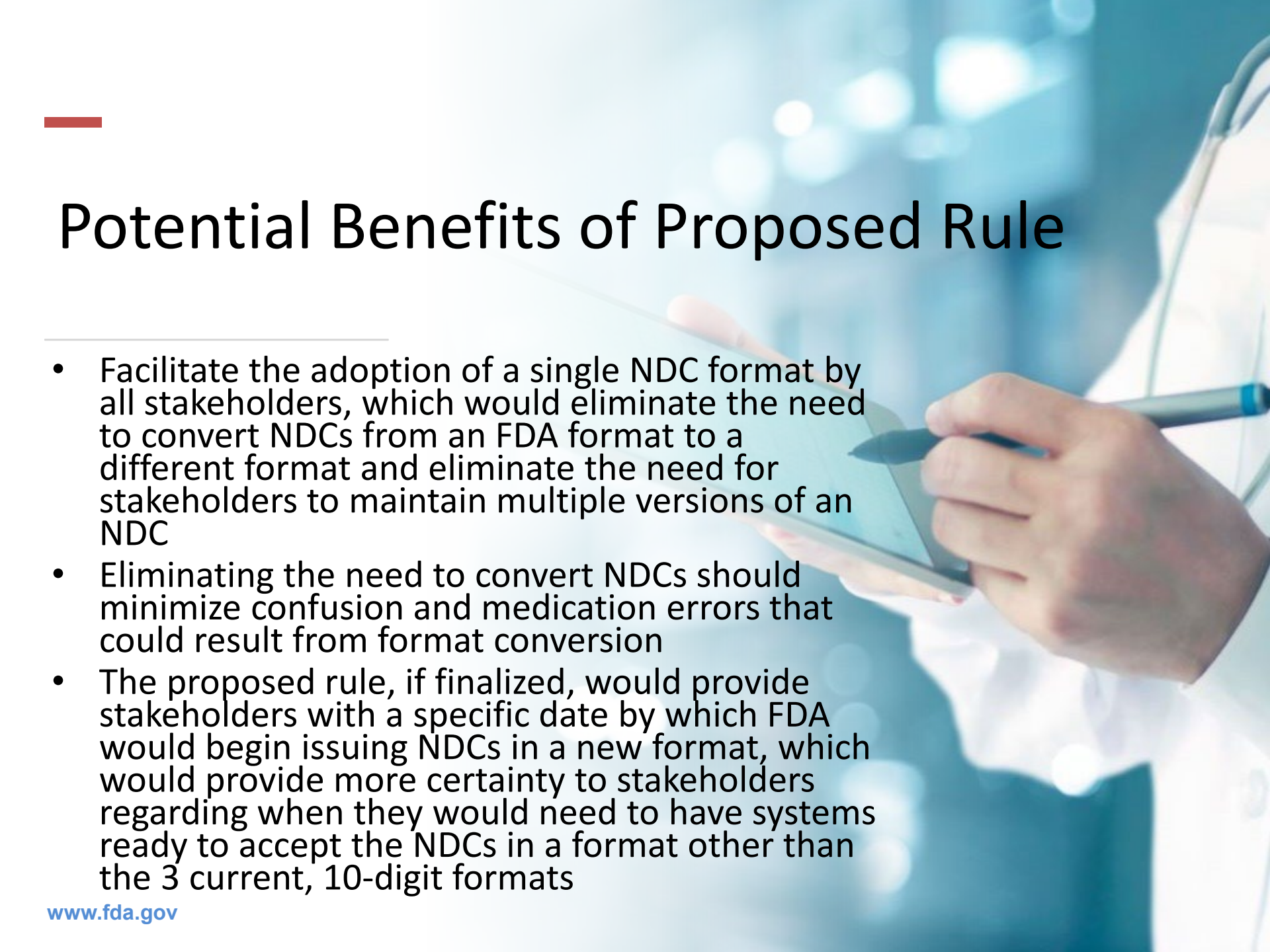
Proposed Rule Overview

- Proposed rule, if finalized, would update the length of NDCs
- Under the proposed rule, if finalized, NDCs would expand from 10 digits to 12 digits
- Drug product barcode labeling requirements would be updated, if the proposed rule is finalized

Proposed National Drug Code (NDC) Change

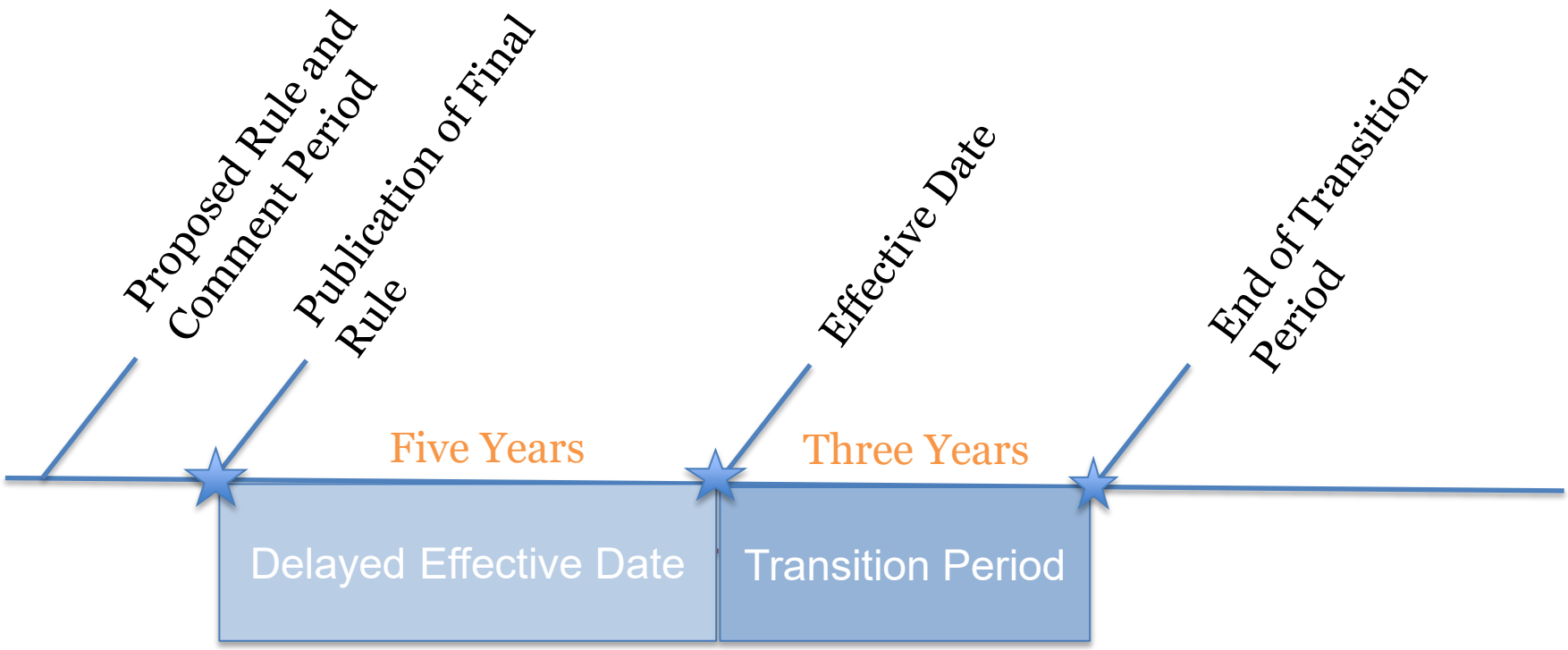


Potential Benefits of Proposed Rule



- Facilitate the adoption of a single NDC format by all stakeholders, which would eliminate the need to convert NDCs from an FDA format to a different format and eliminate the need for stakeholders to maintain multiple versions of an NDC
- Eliminating the need to convert NDCs should minimize confusion and medication errors that could result from format conversion
- The proposed rule, if finalized, would provide stakeholders with a specific date by which FDA would begin issuing NDCs in a new format, which would provide more certainty to stakeholders regarding when they would need to have systems ready to accept the NDCs in a format other than the 3 current, 10-digit formats

Proposed Timeline



Proposed Timeline

- Final rule would include an effective date
  - As proposed the effective date would be five years after final rule publishes
- Provides a 3-year transition period to facilitate a smooth transition
  - Minimize relabeling costs
  - Decrease risk of drug shortage due to timing of product release
  - Limit timeframe of confusion with coexisting labeling with 2 NDC formats

Effective Date

- If finalized as proposed on the effective date:
  - FDA would convert all NDCs to 12 digits
  - FDA would begin assigning 6-digit labeler codes and NDCs in the new 12-digit format
  - Stakeholders should have systems capable of handling the new, uniform, 12-digit NDC
  - Firms should start labeling drugs that were assigned 10-digit NDCs with new 12-digit NDC format
  - Drug listing submissions would be required to use the new 12-digit NDC format

Transition Period

- FDA is proposing a 3-year transition period following the effective date
- During the transition period:
  - FDA would publish and maintain both 10- and 12- digit NDCs
  - FDA does not intend to object if drugs that were assigned a 10-digit NDC prior to the effective date continue to be labeled with the 10-digit NDC
  - FDA encourages manufacturers and distributors to include 12-digit NDCs on their drug labeling as soon as possible after the effective date but not later than when the firm runs out of its existing labeling inventory for the drug, and orders or begins printing new labeling
- Under the proposed rule, at the end of the transition period, all firms would be required to use a 12-digit NDC in listing files
  - FDA would no longer exercise enforcement discretion with respect to the 12-digit NDC format requirement for all products that include the NDC on their labeling that are introduced or offered for introduction into interstate commerce

Stakeholder Preparation and Implementation

- Operating systems compatibility (if rule finalized)
  - Have all systems ready to accommodate 12-digit NDCs in 6-4-2 format
- Labeling (if rule finalized)
  - Plan labeling updates and annual reports according to the rule's effective date
- Drug Listing (if rule finalized)
  - Confirm 12-digit NDC format after effective date
  - Provide updated labeling for your drug listing files after the effective date

Comments

- Comment period ended on November 22, 2022
- Comments submitted to this docket can be viewed: https://www.regulations.gov/docket/FDA-2021-N-1351/document
- Federal Register Notice *Revising the National Drug Code Format and Drug Label Barcode Requirements* (Docket No. FDA-2021-N-1351)
- Revising the National Drug Code Format and Drug Label Barcode Requirements (Proposed Rule) Regulatory Impact Analysis, Federal Register 87 FR 44038

Challenge Question #1

The 11-digit HIPPA NDC is converted by:

a. Adding a leading zero at the beginning

b. Adding a tailing zero at the end

c. Adding a leading zero in the short segment of the NDC

d. Adding an extra digit anywhere

Challenge Question #2

The length of the transition period is

a. 5 years

b. 3 years

c. 8 years

d. 12 years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