Supply Chain Security and Upcoming NDC Changes

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Office of Compliance
CDER | US FDA

NCPA Webinar
November 2022

Disclaimer

This presentation is intended only to provide a general overview. It is not intended to be comprehensive, nor does it constitute legal advice. Please refer to appropriate guidelines, regulations, or law for specific information.

Additional Resources

Updates and links to FDA documents or notices summarized in this presentation can be found FDA's website.

Objectives

- Review the requirements of the Drug Supply Chain Security Act (DSCSA) to protect the supply chain
- Describe steps for handling suspect and illegitimate products for supply chain security
- Summarize proposed rule for format revisions to the NDC and barcode requirements

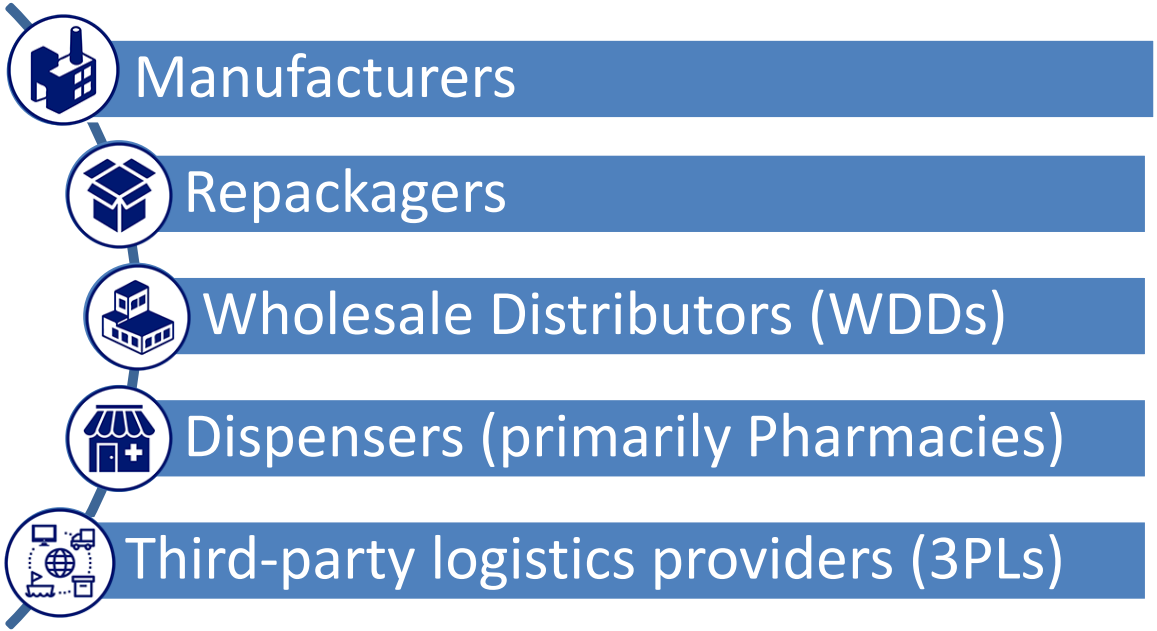
The Drug Supply Chain Security Act DSCSA

- Enacted November 27, 2013
- Outlines steps to achieve interoperable, electronic tracing of product at the package level to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Improves detection and removal of potentially dangerous drugs from the drug supply chain
- Establishes national licensure standards for wholesale drug distributors and third-party logistics providers (3PLs)

DSCSA Key Requirements

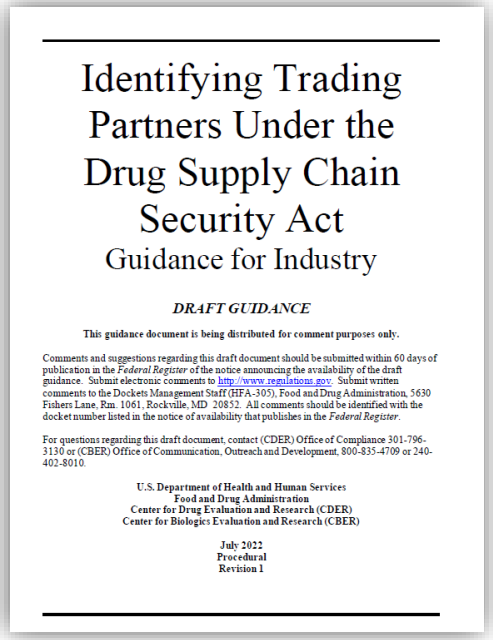
The requirements under section 582 of the FD&C Act apply to manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies).

Trading Partners under DSCSA



Identifying Trading Partners

- Assists industry and State and local governments in understanding how to categorize the entities in the drug supply chain in accordance with the DSCSA
- Addresses the status of some entities as trading partners *(e.g., private-label distributors, salvagers, and returns processors and reverse logistics providers)*
- Provides clarification of certain drug distribution scenarios
- Discusses third-party logistics providers (3PL) licensure status prior to the effective date of the forthcoming regulations establishing licensure standards



Identifying Trading Partners Under the Drug Supply Chain Security Act

Guidance for Industry

DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

July 2022
Procedural
Revision 1

Dispensers under DSCSA

Dispensers (primarily pharmacies)

- A retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership or control, or
- Any other person authorized by law to dispense or administer prescription drugs, and
- Affiliated warehouses or distribution centers of such entities.
- Excludes:
  - if such entity acts as a wholesale distributor;
  - a person who only dispenses products used in animals.

Refer to definition for "dispenser" in section 581(3) of the FD&C Act.

Dispensers Requirements

Retail pharmacy, hospital pharmacy, or chain pharmacies

- Product tracing, product identifier, authorized trading partner, verification
- See section 582(d)(1), (2), (3) and (4) of the FD&C Act

Any other person authorized by law to dispense or administer prescription drugs

- Product tracing and verification requirements shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice…
- See exception under section 582(d)(5) of the FD&C Act

DSCSA Implementation

2015

Authorized Trading Partners

- Manufacturers and Repackagers: valid registration with FDA
- WDDs & 3PLs: valid State or Federal license and compliance with reporting requirements
- Dispensers: valid State license

2015

Product Tracing

- Lot-level
- Provide and receive transaction documentation with each sale
- Respond to request for information
- Store records
- Paper and electronic formats

2015

Verification

- Quarantine and investigate suspect product
- Investigation illegitimate product
- Notify FDA and trading partners of illegitimate product
- Response to verification requests
- Store records

Product Identifier (Serialization)

Manufacturers/Repackagers (November 2018)

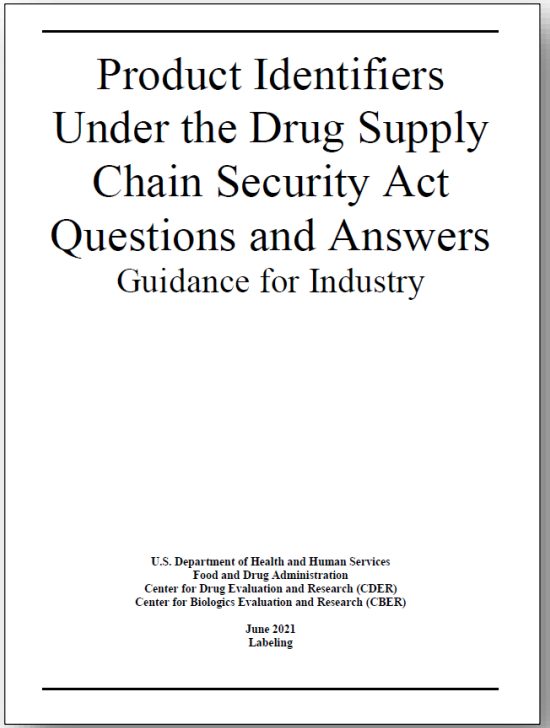
- Encode product identifiers on prescription drug packages
- Determine smallest individual saleable unit
- Verification requirements changes once products are serialized with product identifier

Product Identifier

- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Human and machine-readable formats

Machine readable barcodes:
- 2D data matrix for packages
- Linear or 2D data matrix for homogenous cases


Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2021
Labeling

Packages Without Product Identifiers

Excluded Products	Not all prescription drugs are required to have a product identifier and are excluded.
Grandfathered	Some products will be in the supply chain before the product identifier requirement took effect.
Waiver, Exception or Exemption	Some products were granted a waiver, exception or exemption from the product identifier requirement.

If you are unsure whether a product should have a product identifier, verify with the manufacturer or repackager.

DSCSA Implementation

2018
Product Identification (Serialization)

Manufacturers & repackagers encode product identifiers on prescription drug packages on the smallest individual saleable unit

Product Identifier: National Drug Code (NDC), Serial Number, Lot, Expiration Date)

2018+
Verification

- Serialized product can be verified down to the package level using the product identifier
- Saleable returns
- Compliance policies issued that provide additional time

2023+
Enhanced Drug Distribution Security Requirements

- All electronic
- Enhanced product tracing at the package level (i.e., includes product identifier)
- Enhanced verification

DSCSA Guidances

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies

Enhanced Drug Distribution Security Effective 11/27/2023

Section 582(g) of the FD&C Act

(1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required-

(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

Enhanced Drug Distribution Security Effective 11/27/2023

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(D) The systems and processes necessary to **promptly respond with the transaction information and transaction statement for a product upon a request** by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

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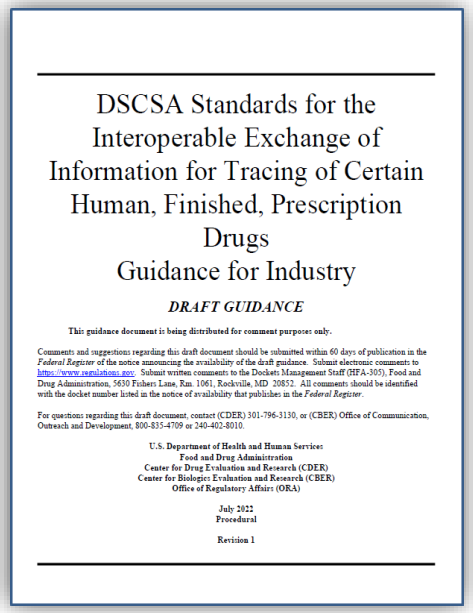
(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can **associate the saleable return product with the transaction information and transaction statement** associated with that product.

Standards for Interoperable Exchange



DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs
Guidance for Industry

DRAFT GUIDANCE

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Office of Regulatory Affairs (ORA)

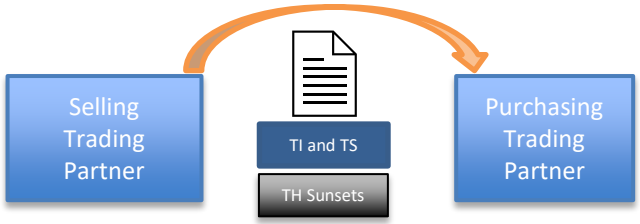
July 2022
Procedural

Revision 1

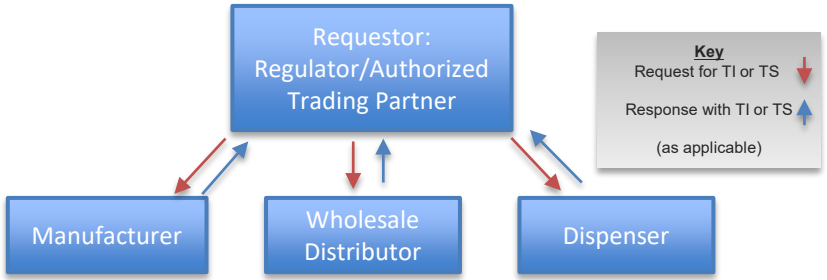
- Identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain
- Updates the policy articulated in the November 2014 draft guidance to reflect the enhanced drug distribution security requirements that will go into effect on November 27, 2023, including that paper-based methods of product tracing will no longer be permitted and verification of product at the package level will be required (unless a waiver, exception, or exemption applies)

Enhanced Product Tracing

Beginning 11/27/2023 - Exchanging and Responding to Request for Product Tracing Information



Transaction information (TI) and the transaction statements (TS)…shall be exchanged in a secure, interoperable, electronic manner…
[Section 582(g)(1)(A) of the FD&C Act]



Promptly respond with the TI and TS...upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product
[Section 582(g)(1)(D) of the FD&C Act]

Promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable…
[Section 582(g)(1)(E) of the FD&C Act]

Enhanced Product Tracing

Beginning 11/27/2023 - Serialized Transaction Information

Transaction information…shall include the product identifier at the package level for each package included in the transaction. *[Section 582(g)(1)(B) of the FD&C Act]*

Pre-November 2023

Transaction Information:

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

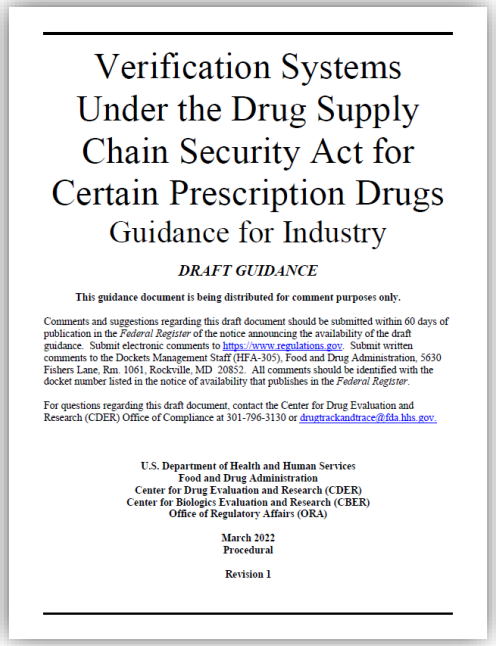
November 2023+

Transaction Information:

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred
- Serial number
- Expiration date

Verification Systems

- Provides recommendations for a robust verification system for determination, quarantine, and investigation of suspect products, and quarantine, notification, and disposition of illegitimate products
- Recommends how trading partners submit cleared product notifications to FDA
- Addresses verification, including saleable returns, at the package level for product identifiers on packages and homogenous cases intended to be introduced in a transaction into commerce



Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

March 2022
Procedural

Revision 1

Verification Requirements

Suspect Product: ***reason to believe*** that product potentially is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Illegitimate Product: ***credible evidence*** shows that the product is:

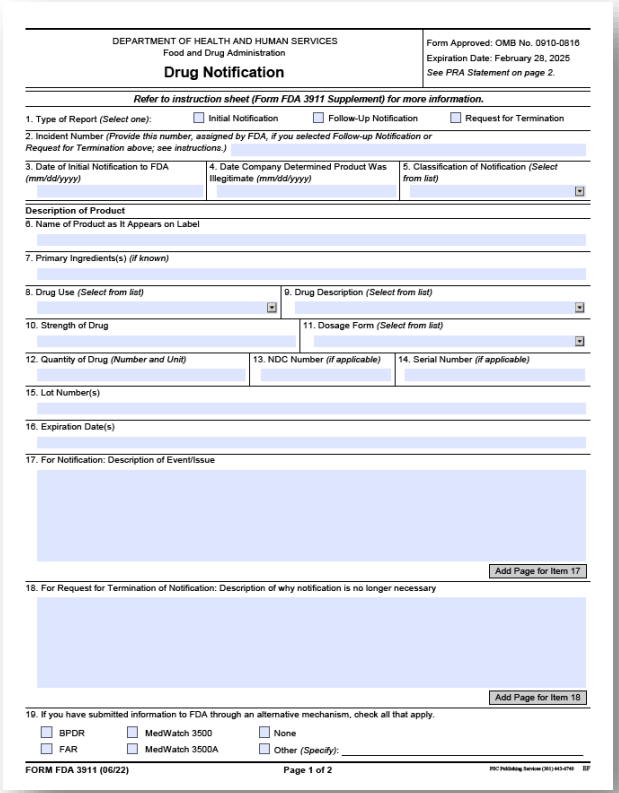
- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Notify FDA of Illegitimate Product within 24 hours (Form FDA 3911) and other trading partners within 24 hours

Reminder: Additional guidances related to verification requirements

- *Identification of Suspect Product and Notification* Final Guidance
- *Definitions of Suspect Product and Illegitimate Product for Verification Obligations…* Draft Guidance

Drug Notifications for Illegitimate Product



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Drug Notification

Form Approved: OMB No. 0910-0816
Expiration Date: February 28, 2025
See PRA Statement on page 2.

Refer to instruction sheet (Form FDA 3911 Supplement) for more information.

1. Type of Report *(Select one)*: ☐ Initial Notification ☐ Follow-Up Notification ☐ Request for Termination

2. Incident Number *(Provide this number, assigned by FDA, if you selected Follow-up Notification or Request for Termination above; see instructions.)*

3. Date of Initial Notification to FDA *(mm/dd/yyyy)*

4. Date Company Determined Product Was Illegitimate *(mm/dd/yyyy)*

5. Classification of Notification *(Select from list)*

Description of Product

6. Name of Product as It Appears on Label

7. Primary Ingredients(s) *(if known)*

8. Drug Use *(Select from list)*

9. Drug Description *(Select from list)*

10. Strength of Drug

11. Dosage Form *(Select from list)*

12. Quantity of Drug *(Number and Unit)*

13. NDC Number *(if applicable)*

14. Serial Number *(if applicable)*

15. Lot Number(s)

16. Expiration Date(s)

17. For Notification: Description of Event/Issue

Add Page for Item 17

18. For Request for Termination of Notification: Description of why notification is no longer necessary

Add Page for Item 18

19. If you have submitted information to FDA through an alternative mechanism, check all that apply.

☐ BPDR ☐ MedWatch 3500 ☐ None
☐ FAR ☐ MedWatch 3500A ☐ Other *(Specify)*: _____

FORM FDA 3911 (06/22) Page 1 of 2

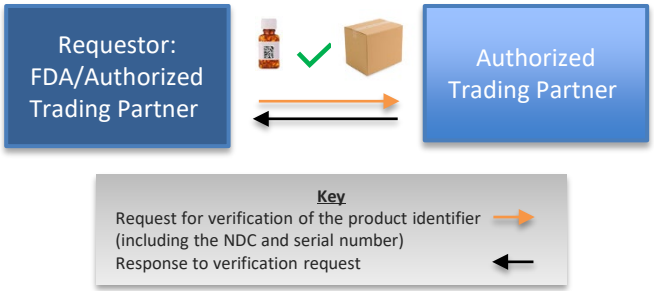
Notify FDA within 24 hours using Form FDA 3911

Notify other trading partners within 24 hours

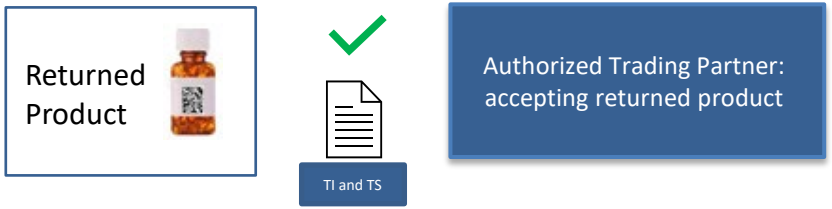
Request notification termination using Form FDA 3911

Enhanced Verification

Beginning 11/27/2023 - Package-Level and Saleable Returns



Systems and processes for verification of product at the package level, including the standardized numerical identifier…in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h)...which may include the use of aggregation and inference as necessary.
[Section 582(g)(1)(C) of the FD&C Act]



Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

[Section 582(g)(1)(F) of the FD&C Act]

Dispensers DSCSA Requirements - Summarized

Product Tracing

- Receive transaction information, transaction history, transaction statement until 2023
- Enhanced product tracing requirements go into effect November 2023 (all electronic)

Product Identifier

- Only buy products encoded with the product identifier
- Note there are drugs that are allowed to not have a product identifier

Authorized Trading Partner

- Only conduct business with an authorized trading partner

Verification

- Quarantine and investigate suspect product
- Disposition and investigate illegitimate product
- Notify FDA and other trading partners of illegitimate product
- Enhanced verification requirements go into effect November 2023

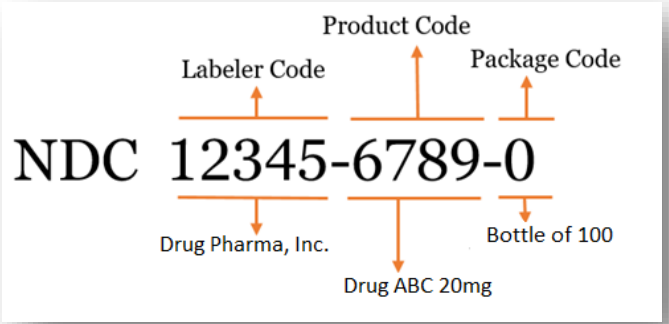
Overview of Proposed Regulations
Revising the National Drug Code Format and Drug Label Barcode Requirements

21 CFR 201
Labeling

21 CFR 207
Requirements for foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a biologics license application, and animal drugs, and the national drug code

NDC Segments and FDA-Assigned Formats Currently In Use

- 3 segments:
  - Labeler code
  - Product code
  - Package code
- 3 FDA-Assigned formats currently in use (referring to number of digits in each segment):
  - 4-4-2
  - 5-3-2
  - 5-4-1



Current NDC Conversion

Health Insurance Portability and Accountability Act (HIPAA)

- 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 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

- 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

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

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

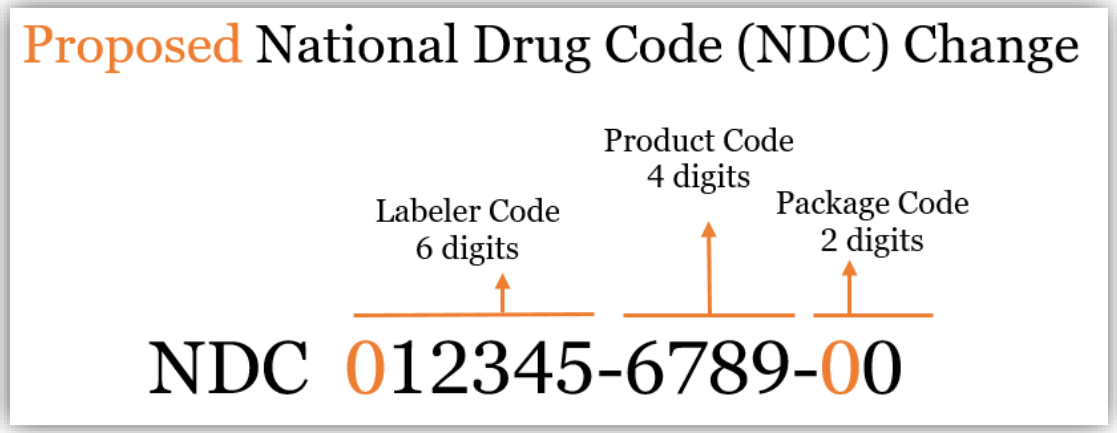
! Two distinct FDA-assigned NDCs for different drug products could result in the same HIPAA 11-digit identifier when hyphens are not used.

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
- State and local governments
- Various supply chain stakeholders
- Others?

Proposed Rule Overview

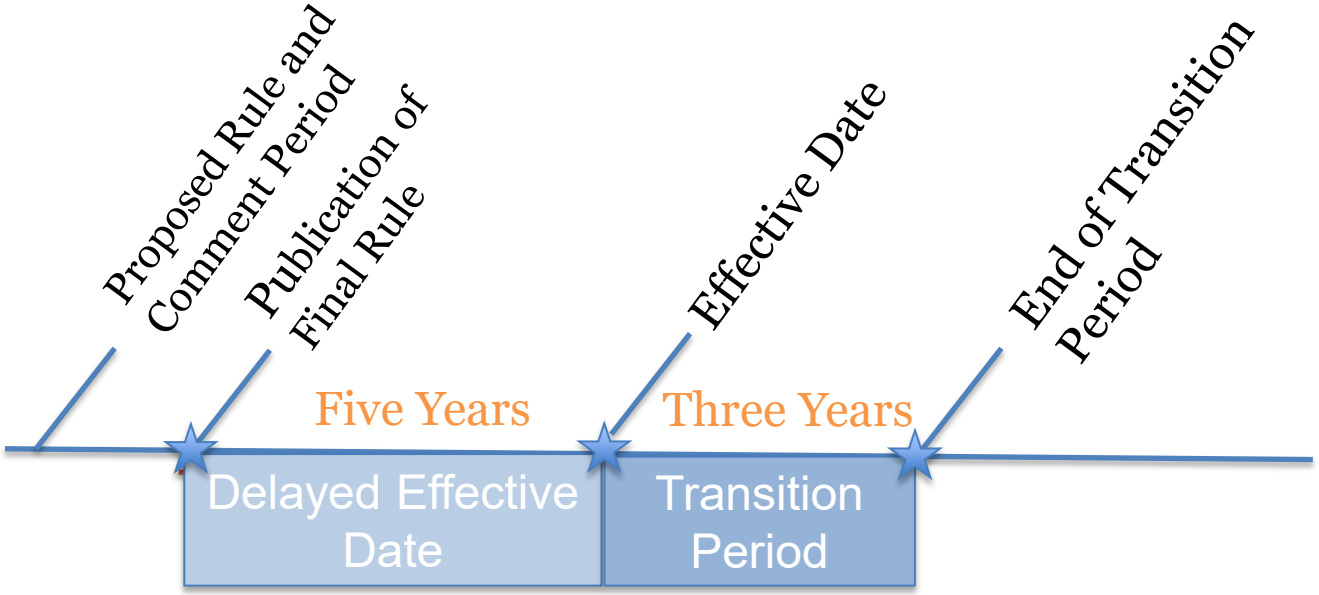
- Proposed rule, if finalized, would update the length of NDCs
- Under the proposed rule, if finalized, NDCs would expand from 10 digits to 12 digits
- Drug product barcode labeling requirements would be updated, if the proposed rule is finalized



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

- **When the final rule is published it would include an effective date**
  - As proposed the effective date would be five years after final rule publishes
- **The proposed 3-year transition period is intended to facilitate a smooth transition by potentially**
  - Minimizing relabeling costs
  - Decreasing the risk of drug shortage
  - Limiting the timeframe during which 10- and 12-digit NDCs coexist

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

Comments Requested on the Proposed Rule: Revising the National Drug Code Format and Drug Label Barcode Requirements

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

FDA Resources

- DSCSA main webpage https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm
- DSCSA regulatory documents (i.e., regulations, guidances, federal register notices) https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm
- Proposed Rule: Revising the National Drug Code Format and Drug Label Barcode Requirements https://www.fda.gov/drugs/drug-approvals-and-databases/proposed-rule-revising-national-drug-code-format#:~:text=The%20NDC%20is%20the%20FDA,drug%20product%20barcode%20label%20requirements.

What's Next

- **Focus on implementing 2023 enhanced drug distribution security requirements -** ***interoperable, electronic tracing of product at the package level***
- **Guidances for Industry:** Additional guidances still to come and finalization of draft guidances
- **WDD/3PL Proposed Regulation:** Review comments and work to finalize
- **NDC Proposed Regulation:** Review comments and work to finalize
- **Stakeholder Engagement**
  - Outreach and Education: Webinars and Presentations
  - Future FDA public meeting(s)
  - Participation in stakeholder workgroups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