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DSCSA: What Specialty Pharmacies Need to Know

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Disclosures

- We have no relevant financial conflicts of interest to disclose in relation to this activity.

Pharmacist and Pharmacy Technician Learning Objectives

- At the completion of this presentation, the participant will be able to:
  - Explain how the exchange of transactional data will change for specialty pharmacies in 2023
  - Identify package level verification requirements for specialty pharmacies in 2023
  - Define suspect and illegitimate product and the processes for identifying and investigating suspect product.

Assessment Question #1

True or false, A suspect product is when the dispenser has a reason to believe that the product is potentially:

- Counterfeit, diverted, or stolen;
- Subject to a fraudulent transaction;
- Intentionally adulterated; or
- Appears otherwise unfit for distribution such that would result in serious adverse health consequences or death in humans

A: True

B. False

Source: Title II of the Drug Quality and Security Act, Sec 581(21). Available at: Title II of the Drug Quality and Security Act | FDA

Assessment Question #2

Which of the following are components of illegitimate product verification?

- Disposition and/or assist with dispositioning product
- Retain sample upon request of HHS Secretary or manufacturer
- Notify the HHS Secretary and immediate trading partners of illegitimate product within 24 hours
- Upon receiving notice take same actions as for suspect product
- Recordkeeping is same as for suspect product
- All of the above

Source: What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act (DSCSA)? | FDA

Assessment Question #3

What are the new interoperability requirements?

- Must electronically exchange transaction information and transaction statement for drug product package in a secure and interoperable manner
- Transaction information must include product identifier at the package level
- Systems and processes for verification at the package level
- Must maintain systems to provide transaction information and transaction statement in response to requests for recalls or suspect & illegitimate investigation
- Systems to promptly facilitate gathering of information needed to produce transaction information going back to the manufacturer
- Systems and processes to associate saleable return product
- All of the above

Source: DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs (fda.gov)

Agenda

- Overview
- Recent Developments
- Future Considerations

Overview

Background of DSCSA

- Enacted in 2013
  - Over 10 years (ending in 2023)
- Goals:
  - Track and trace system – uniform, electronic, interoperable
  - Suspect and illegitimate products (package level)
  - More efficient recalls
  - Federal licensing standards

Affected Stakeholders

- Drug Manufacturers
- Wholesale Drug Distributors
- Third-Party Logistics Providers (3PLs)
- Repackagers
- Dispensers

Source: Title II of the Drug Quality and Security Act | FDA, Section 581.

Covered vs. Not Covered Under DSCSA

Covered

- Products: Prescription drug in finished dosage form for administration to a patient without further manufacturing
  - E.g., capsules, tablets, lyophilized products before reconstitution

Not Covered

- Over-the-counter, medical devices, active pharmaceutical ingredients, or animal drugs
- Blood and blood components
- Radioactive drugs/biologics
- Imaging drugs
- Intravenous products
- Medical gases
- Compounded drugs

Source: Title II of the Drug Quality and Security Act, Sec 581(13). Available at: Title II of the Drug Quality and Security Act | FDA

Transaction and Traceability

- Transaction = product that changes ownership
  - Traceability requirements apply to transactions
- Traceability requirements = “The 3 Ts”
  - Transaction information (TI)
  - Transaction history (TH) - phased out in 2023/2024
  - Transaction statement (TS)

Source: Title II of the Drug Quality and Security Act | FDA, Section 581.

Exemptions

- Specific patient need
- Office use
- Mergers
- Combination products
- Emergencies

Source: Title II of the Drug Quality and Security Act, Sec 581(19); 581(24)(B). Available at: Title II of the Drug Quality and Security Act | FDA

Tracing Requirements

- Receive and capture transaction information / transaction history / transaction statement
- Provide transaction information / transaction history / transaction statement
- Store 6 years of records
- Respond to information request
- Return product to trading partner
- Enhanced Drug Distribution Security requirements (2023/2024)

Source: What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act (DSCSA)? | FDA

Serialized IDs

- Only accept ownership of products with a DSCSA-compliant identifier
- Grandfathered product
- Manufacturers and repackagers may have an exception to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information

Source: Title II of the Drug Quality and Security Act, Sec 582(a)(3). Available at: Title II of the Drug Quality and Security Act | FDA

DSCSA Compliant Product Identifier

- 2D barcode or “data matrix”
- Section 582(a)(9) of FD&C Act

- Human-readable elements:
  - National Drug Code (or NDC)
  - Serial number
  - Lot number
  - Expiration date

Source: https://www.fda.gov/media/101406/download

Authorized Trading Partners

- Only deal with Authorized Trading Partners

- Authorized Trading Partners must be:
  - Licensed (pharmacies, wholesale distributors and third-party logistics providers) or
  - Registered (manufacturers and repackagers)

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients

Suspect Product

- Dispenser has **reason to believe is potentially**:
  - Counterfeit, diverted, stolen;
  - Subject to fraudulent transaction;
  - Intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

Source: Title II of the Drug Quality and Security Act, Sec 581(21). Available at: Title II of the Drug Quality and Security Act | FDA

Illegitimate Product

- Dispenser has **credible evidence that shows**:
  - Product is counterfeit, diverted, stolen
  - Subject of fraudulent transaction
  - Intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

Source: Title II of the Drug Quality and Security Act, Sec 581(8). Available at: Title II of the Drug Quality and Security Act | FDA

Suspect Product Verification

- Identify suspect product
- Quarantine and investigate suspect product
  - Verify product data
  - Validate transaction history and transaction information
- Document and maintain investigation report for 6 years

Source: What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act (DSCSA)? | FDA

Illegitimate Product Verification

- Illegitimate Product
  - Disposition and/or assist with dispositioning product
  - Retain sample upon request of HHS Secretary or manufacturer
  - Notify the HHS Secretary and immediate trading partners of illegitimate product within 24 hours
  - Upon receiving notice take same actions as for suspect product
  - Recordkeeping is same as for suspect product

Source: What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act (DSCSA)? | FDA

Stop and Think Question

- If you receive a product with misspellings on the label or is missing information on the label that you would expect to see, what action would you take, as a pharmacist?

Penalties

- Failure to comply with a DSCSA requirement is a “prohibited act”
- Lack of a product identifier is misbranding
- Commission of a prohibited act subjects a party to:
  - Injunction of unlawful activity
  - Seizure of goods
  - Civil and criminal fines and penalties (including jail)

Source: Title II of the Drug Quality and Security Act, Sec 206. Available at: Title II of the Drug Quality and Security Act | FDA

Recent and Pending Developments

New DSCSA Requirements for 2023/2024

- System attributes:
  - Must electronically exchange transaction information and transaction statement for drug product package in a secure and interoperable manner
  - Transaction information must include product identifier at the package level
  - Systems and processes for verification at the package level
  - Must maintain systems to provide transaction information and transaction statement in response to requests for recalls or suspect & illegitimate investigation
  - Systems to promptly facilitate gathering of information needed to produce transaction information going back to the manufacturer
  - Systems and processes to associate saleable return product

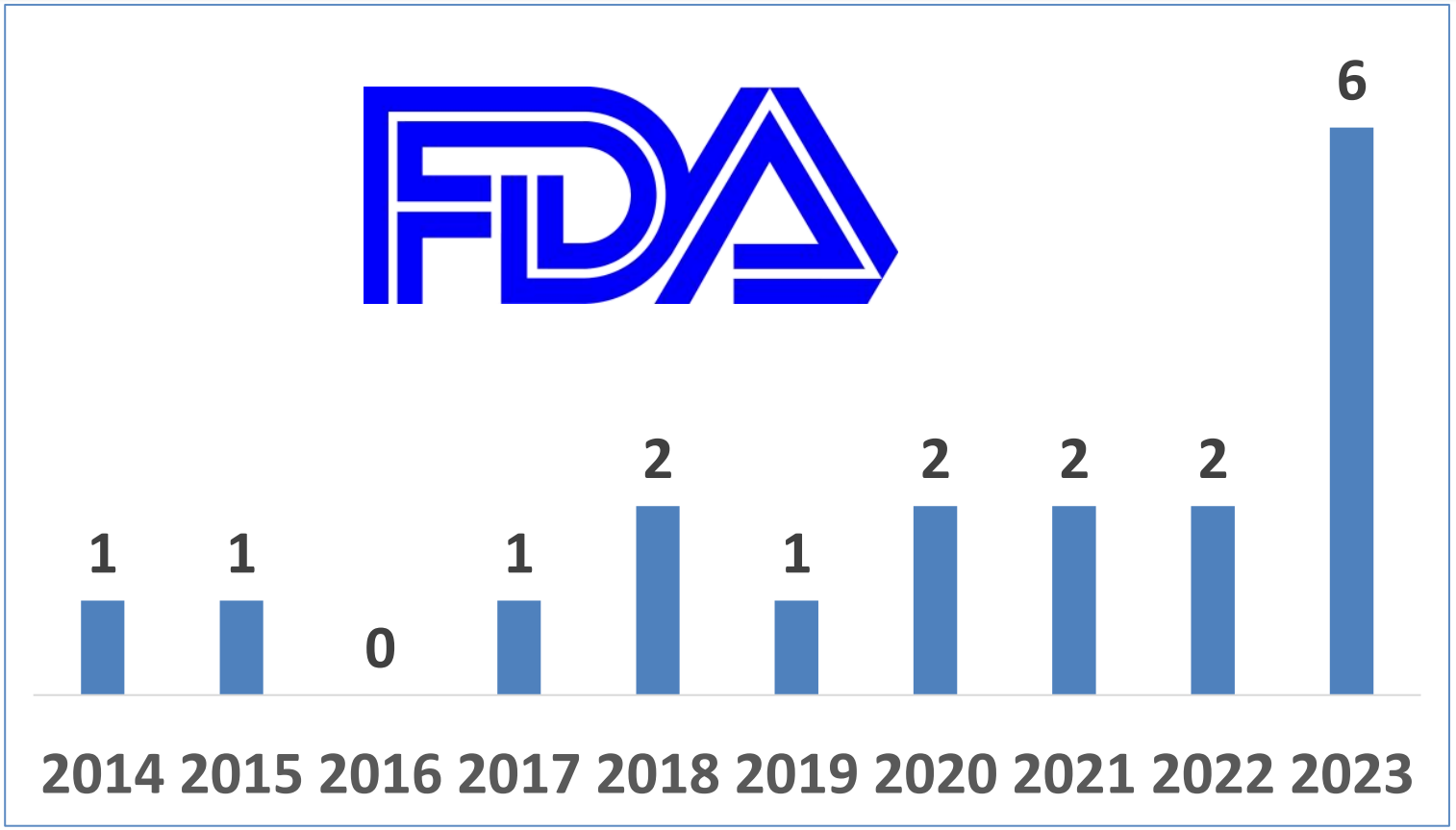
Source: Title II of the Drug Quality and Security Act, Sec 582(g)(1). Available at: Title II of the Drug Quality and Security Act | FDA

New DSCSA Requirements for 2023/2024 (Continued)

- Pharmacies must verify the product identifier of the suspect product of at least three packages or 10 percent of products, or all packages, if there are fewer than 3, under suspect investigation

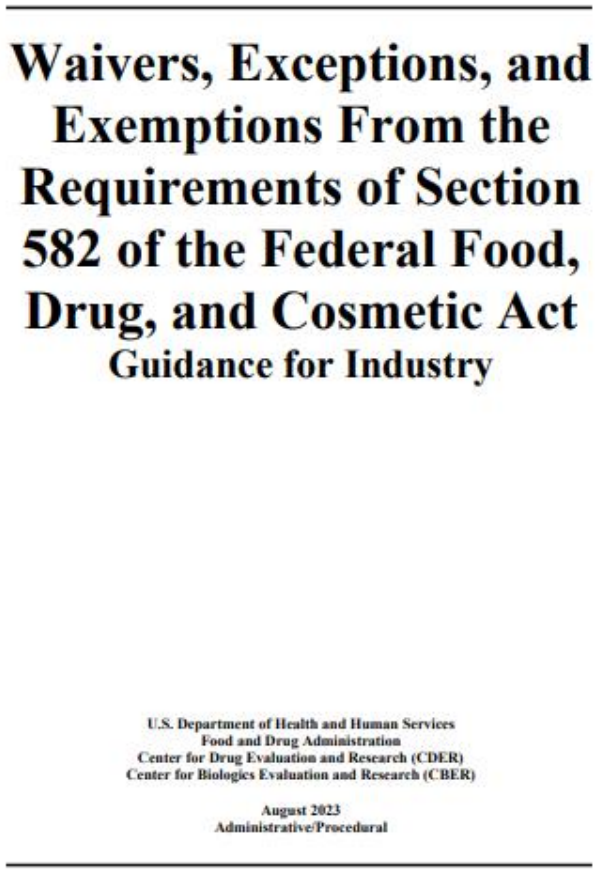
Source: Title II of the Drug Quality and Security Act, Sec 582(d)(4)(A)(ii)(II). Available at: Title II of the Drug Quality and Security Act | FDA

Number of Finalized DSCSA Guidances, By Year



Source: Drug Supply Chain Security Act Law and Policies | FDA

Final Guidance – August 2023



Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act

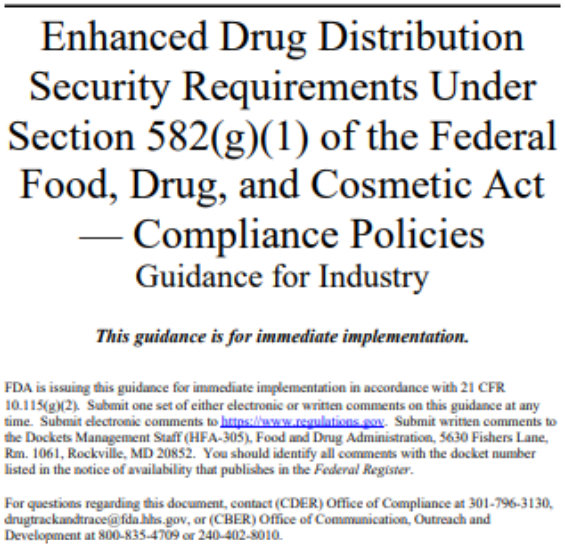
Guidance for Industry

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)

August 2023
Administrative/Procedural

- Requests
  - Who may submit a request
  - Information to include
  - How to submit
- Process for reviewing requests, including reconsideration
- FDA-initiated exceptions/exemptions
- Renewing/terminating approvals

Final Guidance #2: August 2023



Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies

Guidance for Industry

This guidance is for immediate implementation.

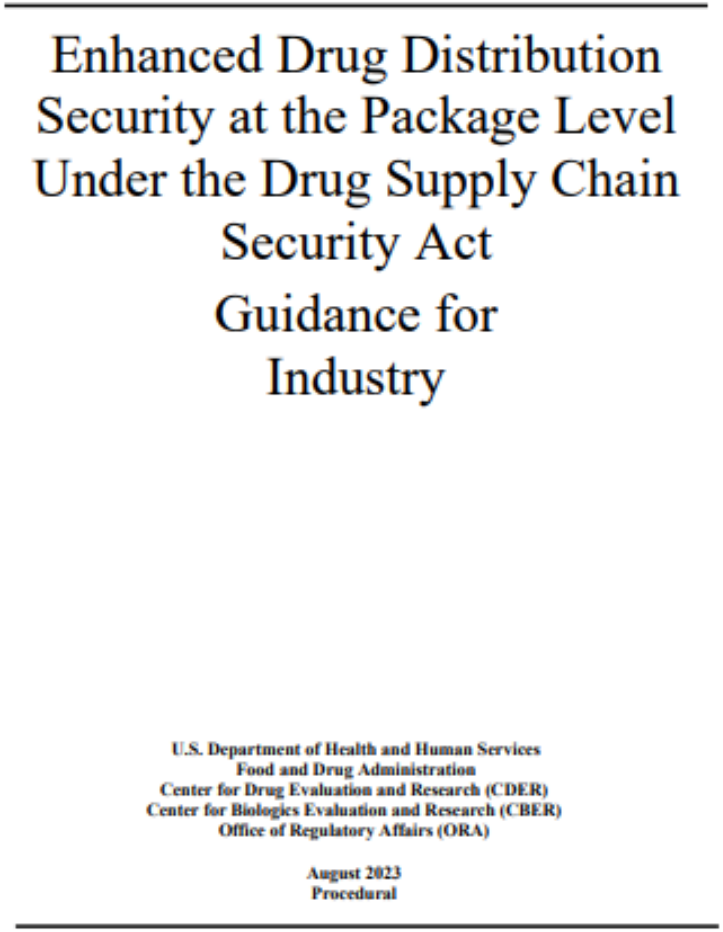
FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact (CDER) Office of Compliance at 301-796-3130, drugtrackandtrace@fda.hhs.gov, or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

- FDA will delay enforcing EDDS until Nov. 27, 2024
- Effective date has **not** changed
- "Stabilization period"

This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Final Guidance #3: August 2023



Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act

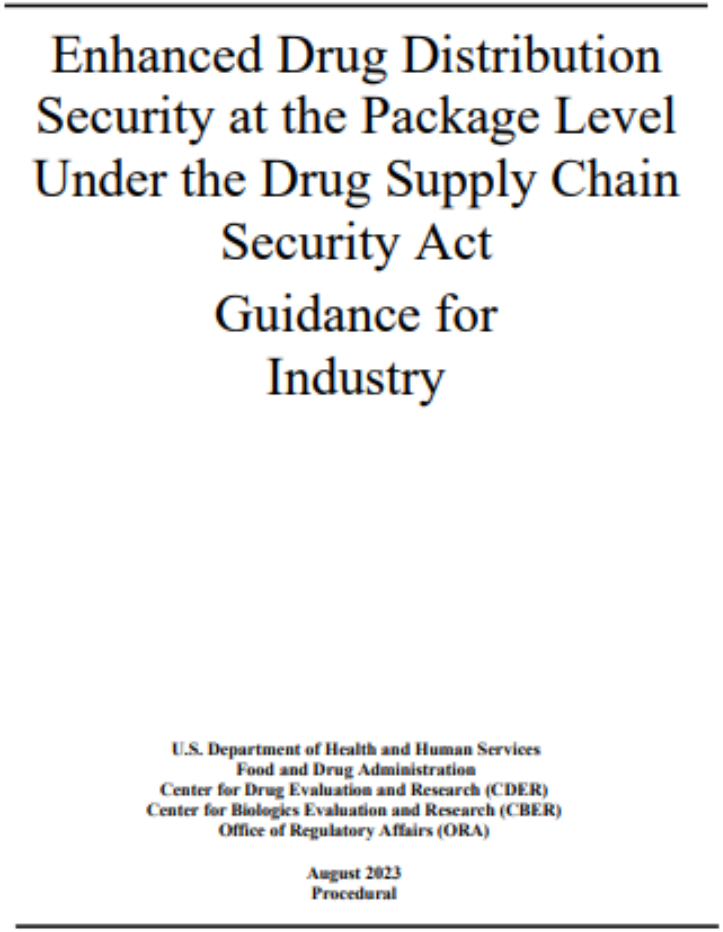
Guidance for Industry

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)
Office of Regulatory Affairs (ORA)

August 2023
Procedural

- EDDS
  - Aggregation and inference for product verification at the package level
  - Security features on shipping units
- System Architecture
  - Recommend distributed or semi-distributed model with EPCIS data standard
  - Data and system security standards
  - Protection of confidential information and trade secrets

Final Guidance #3: August 2023 (Continued)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U.S. Department of Health and Human Services
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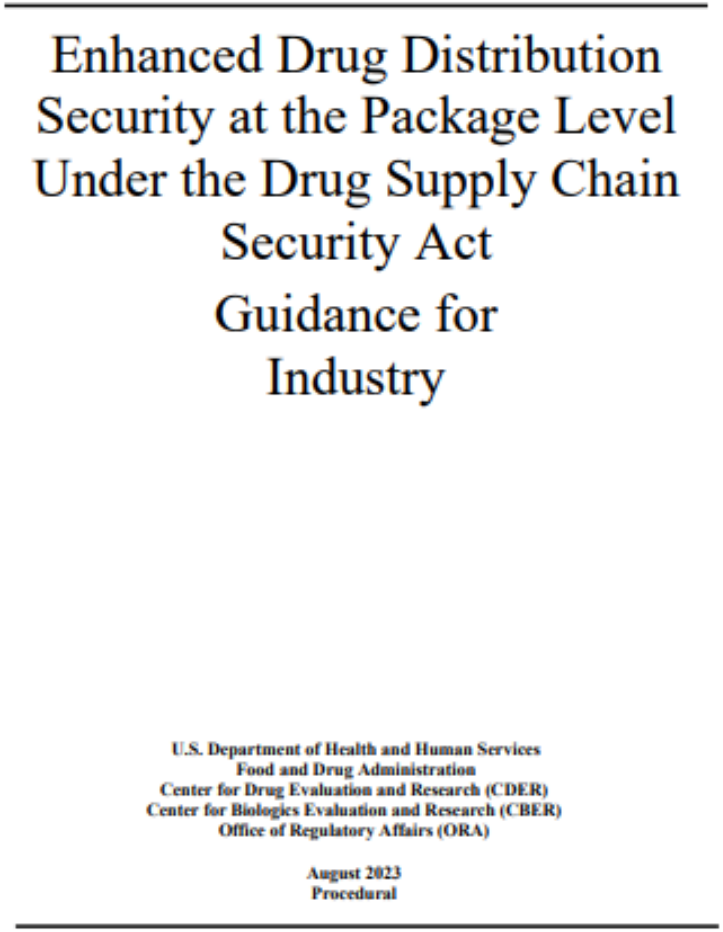
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

August 2023
Procedural

Enhanced Product Tracing

- Individual product identifier must be in the transaction information
- Selling trading partner should reconcile transaction information with product
- Buying trading partner should match transaction information and transaction statement with product
- Data and product discrepancies and how to resolve them

Final Guidance #3: August 2023 (Continued)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Guidance for Industry

U.S. Department of Health and Human Services
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Office of Regulatory Affairs (ORA)

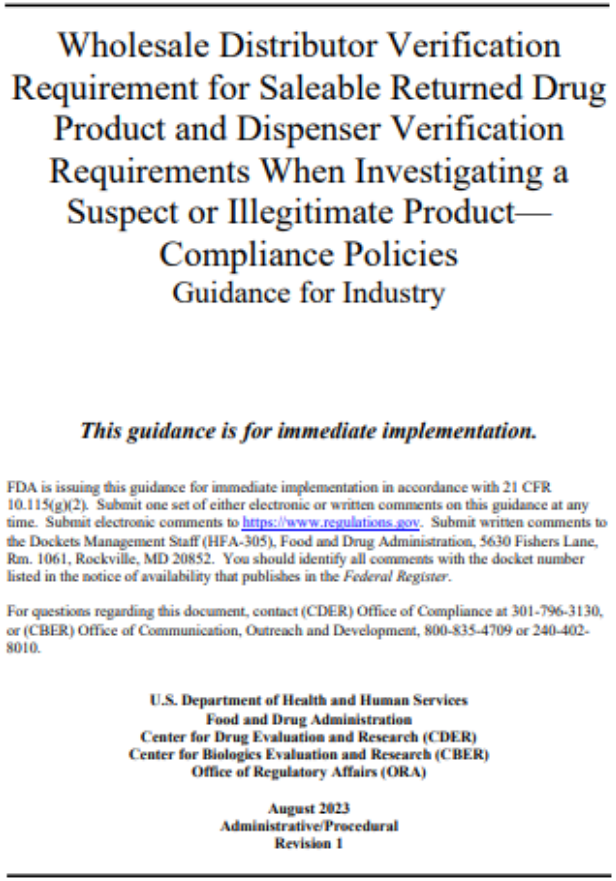
August 2023
Procedural

- Systems and processes to respond to request for transaction information and transaction statement from regulator

vs.

- Systems and processes to facilitate gathering information needed to produce transaction information back to manufacturer upon request from regulator or trading partner
- Verification of distributed product at the package level

Final Guidance #4: August 2023



Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies

Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://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. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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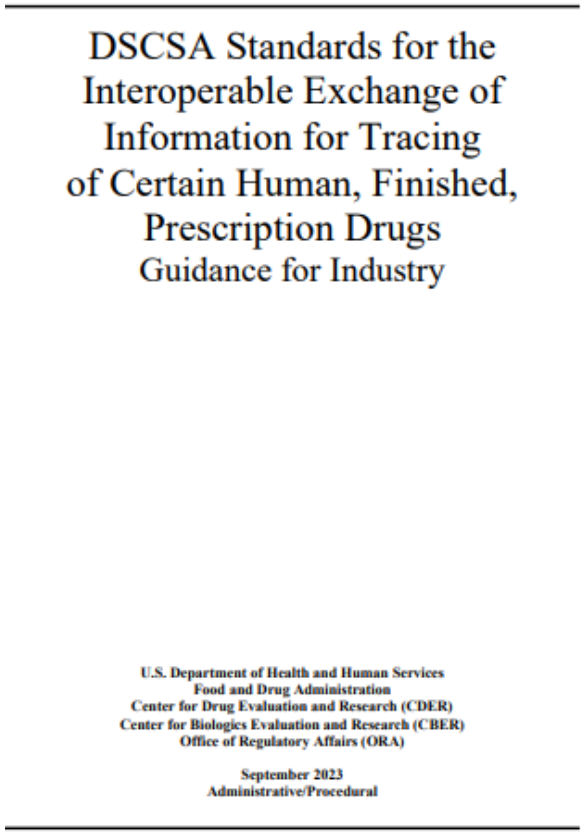
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

August 2023
Administrative/Procedural
Revision 1

- FDA does not intend to take action against dispensers before Nov. 27, 2024 who do not:
  - Verify the product identifier of suspect & illegitimate product of at least three packages or 10 percent of products

Final Guidance: September 2023



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

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)
Office of Regulatory Affairs (ORA)

September 2023
Administrative/Procedural

- Defines interoperability under Enhanced Drug Distribution Security
- Recommended usage of Electronic Product Code Information Services (EPCIS) standard

- In addition to guidance: have a Global Location Number (GLN)

Future Considerations

Industry Seeking Phased Implementation

Source: ASHP DSCSA letter; NCPA NACDS APhA DSCSA letter; HDA DSCSA letter

Small Dispenser Assessment Request for Comment

- Published Aug. 10
  - Comments due Sept. 11
- 25 or fewer full-time equivalents
- Readiness for Nov. 27, 2023 deadline re: software and hardware

Source: 2023-17140.pdf (govinfo.gov)

Ongoing Concerns

- Trading partner readiness issues; specialty concerns
- What does the Enhanced Drug Distribution Security FDA enforcement discretion mean?
  - Liability risks remain
- “The 3 Ts” and misbranded drugs
- 340B
- Enforcement, especially non-FDA enforcement
- Proposed Rule on wholesaler and third-party logistics providers licensing standards

Presentation Summary

- Overview
- Recent Developments
- Future Considerations

Assessment Question #1

True or false, A suspect product is when the dispenser has a <u>reason to believe</u> that the product is potentially:

- Counterfeit, diverted, or stolen;
- Subject to a fraudulent transaction;
- Intentionally adulterated; or
- Appears otherwise unfit for distribution such that would result in serious adverse health consequences or death in humans

<u>A: True</u>

B. False

Source: Title II of the Drug Quality and Security Act, Sec 581(21). Available at: Title II of the Drug Quality and Security Act | FDA

Assessment Question #2

Which of the following are components of illegitimate product verification?

- Disposition and/or assist with dispositioning product
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- **All of the above**

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What are the new interoperability requirements?

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- Systems and processes to associate saleable return product
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Source: DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs (fda.gov)

Questions?

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Alexandria, VA
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Supplemental Resources

- Drug Supply Chain Security Act (DSCSA) | FDA
- Title II of the Drug Quality and Security Act | FDA
- Drug Supply Chain Security Act Law and Policies | FDA
- DispenserEDU
- DSCA Pharmacy Checklist and SOPs Considerations | NCPA
  [member access only]

References

- Title II of the Drug Quality and Security Act. Drug Supply Chain Security. U.S. Food and Drug Administration. Published December 16, 2014. Accessed November 7, 2023. https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act
- What do I need to know about supply chain security requirements under the Drug Supply Chain Security Act (DSCSA)? U.S. Food and Drug Administration. Published August 30, 2023. Accessed November 7, 2023. https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/what-do-i-need-know-about-supply-chain-security-requirements-under-drug-supply-chain-security-act#Quarantine
- DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs 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), Office of Regulatory Affairs (ORA). Published September 6, 2023. Accessed November 7, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs
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- FDA Waives Some Track and Trace Requirements During the Pandemic. ASHP. Accessed November 7, 2023. https://www.ashp.org/-/media/assets/advocacy-issues/docs/GRD-FDA-Waives-Some-Track-and-Trace-Requirements
- NCPA NACDS APhA DSCSA letter. https://ncpa.org/sites/default/files/2023-07/phased-approach-dscsa-letter-fda.pdf
- HDA DSCSA letter. https://ncpa.org/sites/default/files/2023-07/hda-phased-approach-cl.pdf

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