Drug Supply Chain Security Act Changes and Implications for Dispensers

Presenters

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Conflict of Interest Disclosure

- We declare that neither of us, nor any of our immediate family members, have current affiliations or financial arrangements with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

Learning Objectives

- At the completion of this presentation, the participant will be able to:
  - Understand the purpose and requirements of the DSCSA;
  - Identify the key take-aways from the 2023 final guidances;
  - Appreciate the reasons why stakeholders supported delayed and phased implementation

Assessment Question #1

Which of the following is an objective of the DSCSA?

a) Establish a uniform electronic interoperable federal track and trace system from manufacturer to dispenser
b) Establish standards for verification of suspect products, and standards and processes for identification, notification, and handling of suspect and illegitimate products down to package level
c) Enhance detection and notification of illegitimate products in supply chain
d) Facilitate more efficient recalls of drugs
e) All of the above

Assessment Question #2

2. Trade associations representing dispensers and wholesalers support a delayed, stepwise implementation of the DSCSA to ensure that all partners in the supply chain have adequate time to stabilize the complex systems and processes necessary.
   a. True
   b. False

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

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

- OTC, medical devices, API, or animal drugs
- Blood and blood components
- Radioactive drugs/biologics
- Imaging drugs
- Intravenous products
- Medical gases
- Compounded drugs

Transaction and Traceability

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

Exemptions

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

Tracing Requirements

- Receive and capture TI/TH/TS
- Provide TI/TH/TS
- Store 6 years of records
- Respond to information request
- Return product to trading partner
- EDDS requirements (2023/2024)

Serialized IDs

- Only accept ownership of products with a DSCSA-compliant identifier
- Grandfathered product
- Exception for some packaging if product package label is too small

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

Authorized Trading Partners

- Only deal with Authorized Trading Partners
- ATPs must be licensed (pharmacies, wholesale distributors and 3PLs) or registered (manufacturers and repackagers)

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

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

Suspect Product Verification

- Suspect Product
  - Identify suspect product
  - Quarantine and investigate suspect product
    - Verify product data
    - Validate TH and TI
- Document and maintain investigation report for 6 years

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

Penalties

- Failure to comply with a DSCSA requirement is a “prohibited act”
- Lack of a product identifier (PI) 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)

Recent and Pending Developments

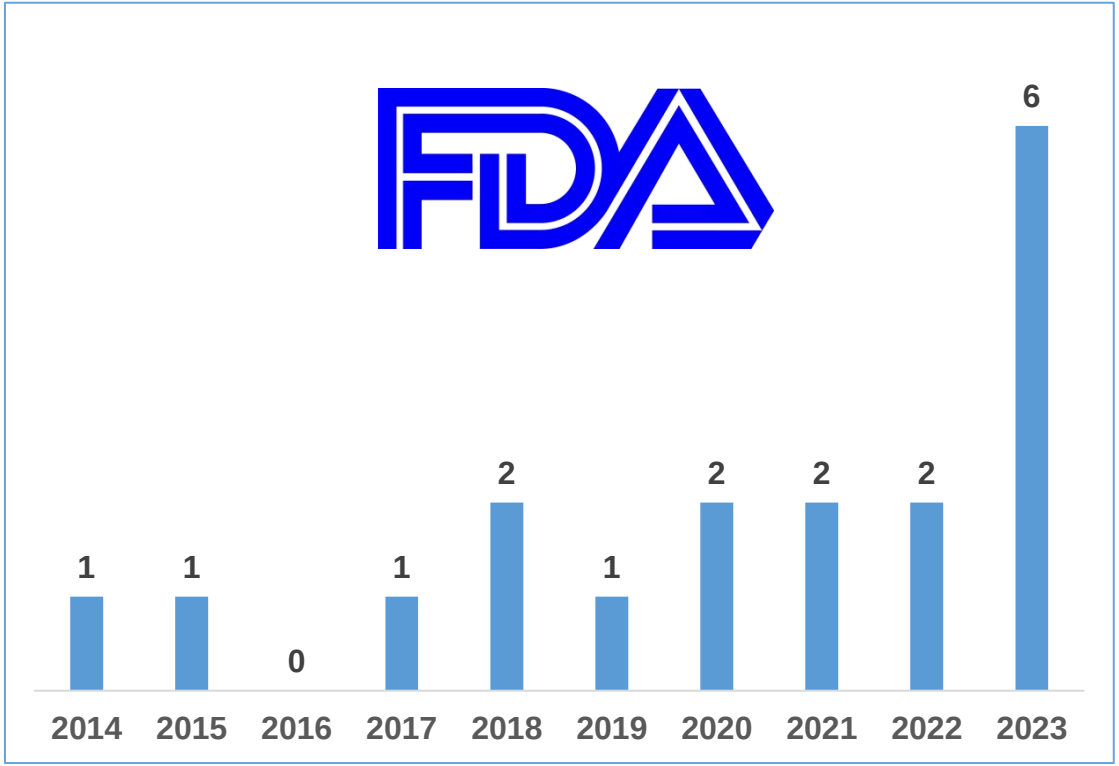
New DSCSA Requirements for 2023/2024

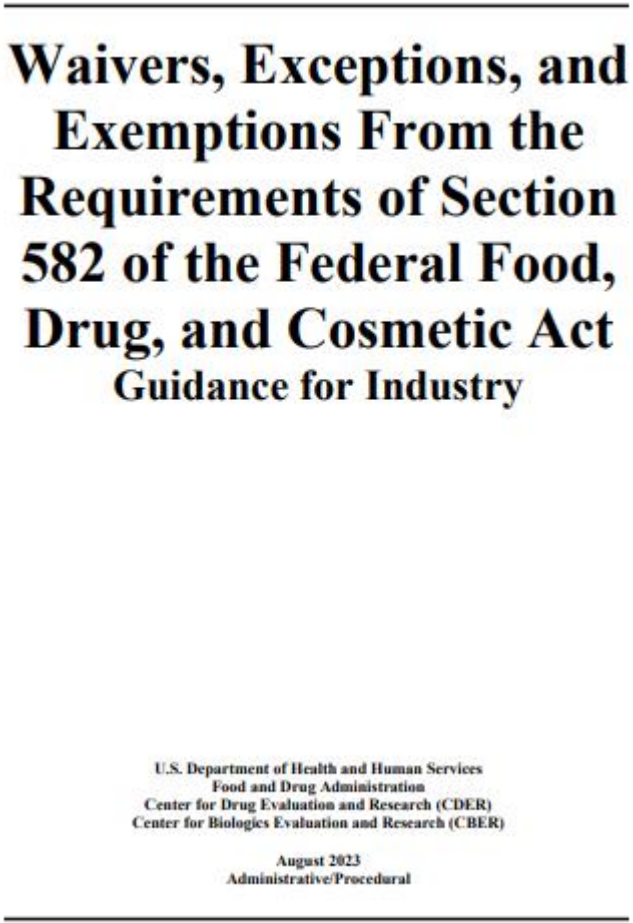
- System attributes:
  - Must electronically exchange TI/TS for drug product package in a secure and interoperable manner
  - TI must include product identifier (PI) at the package level
  - Systems and processes for verification at the package level
  - Must maintain systems to provide TI and TS in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

New DSCSA Requirements for 2023/2024 (Continued)

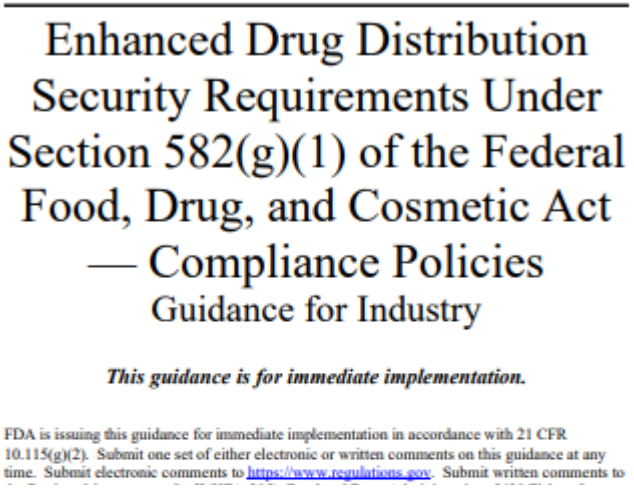
- Pharmacies must verify the product identifier of the suspect product of at least three packages or 10 percent of products under suspect investigation

Number of Finalized DSCSA Guidances, By Year





- 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



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

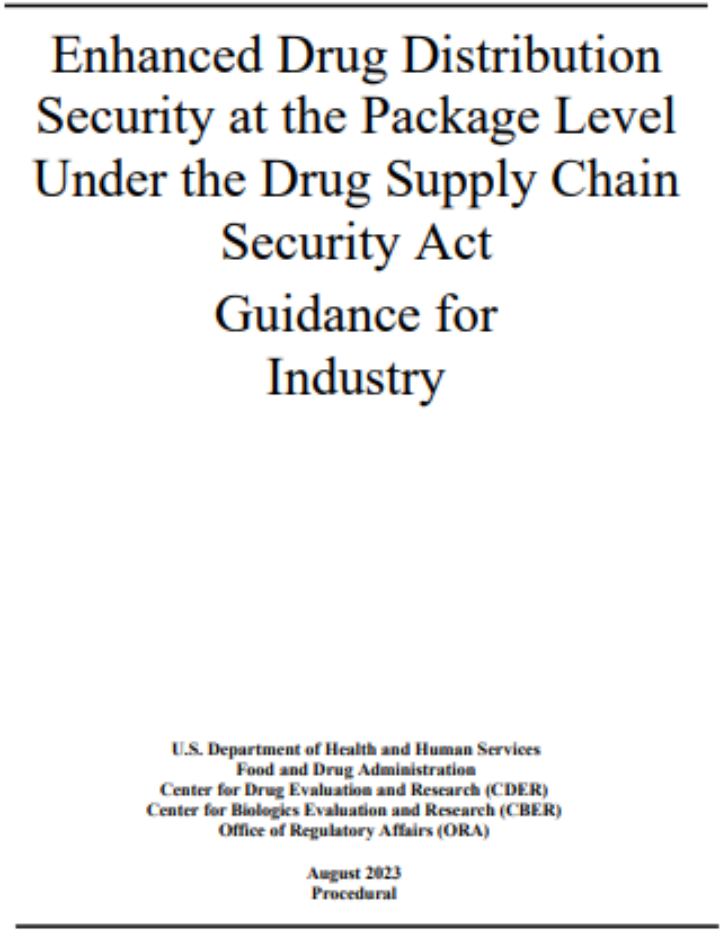
Guidance for Industry

This guidance is for immediate implementation.

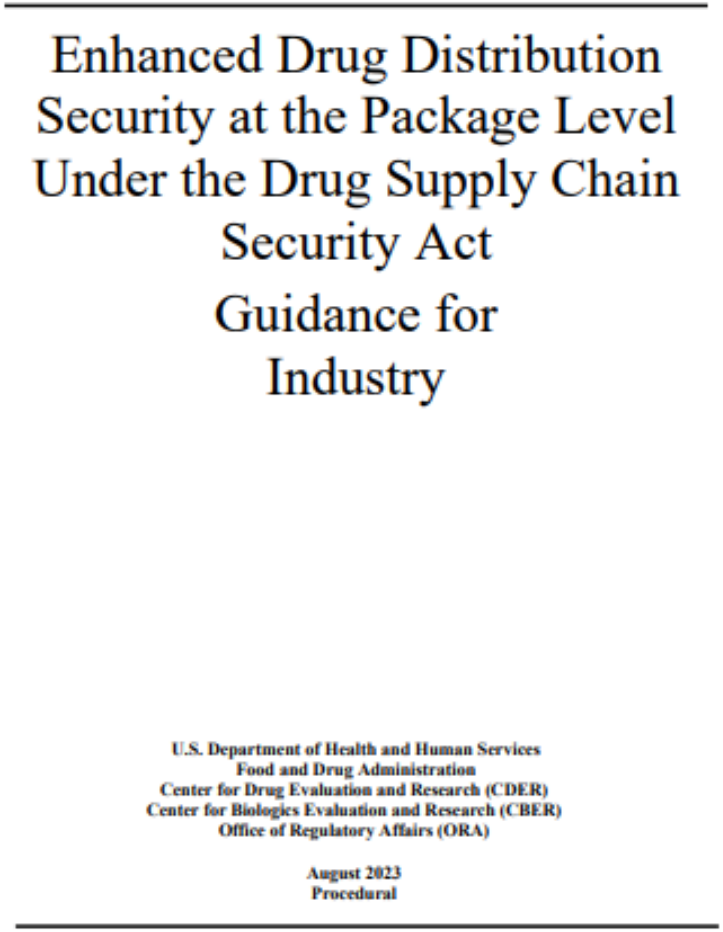
FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to

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.

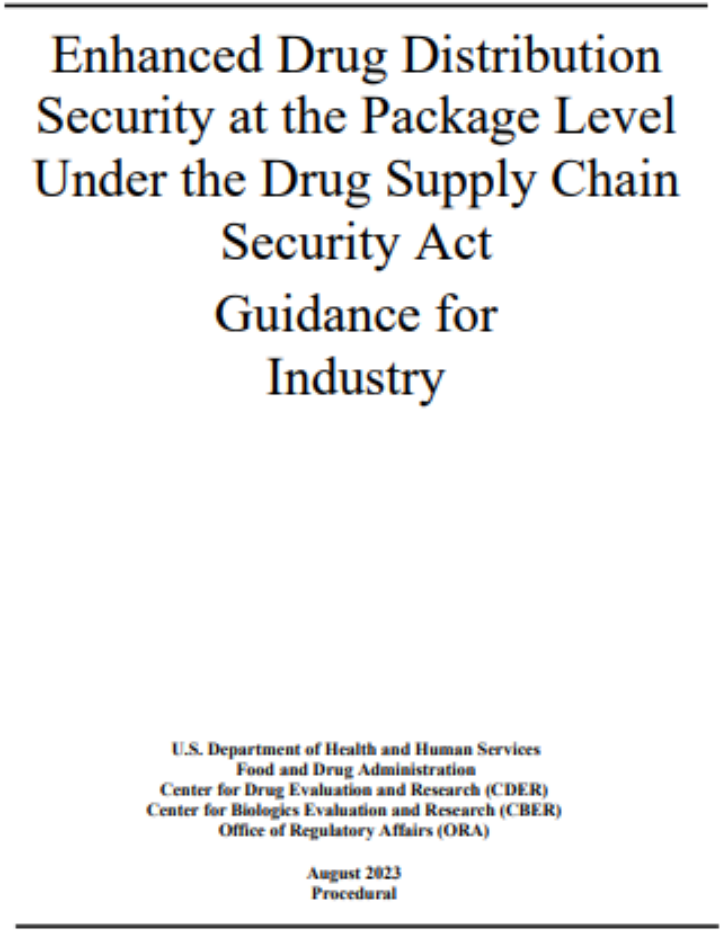
- FDA will delay enforcing EDDS until Nov. 27, 2024
- Effective date has **not** changed
- “Stabilization period”



- 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



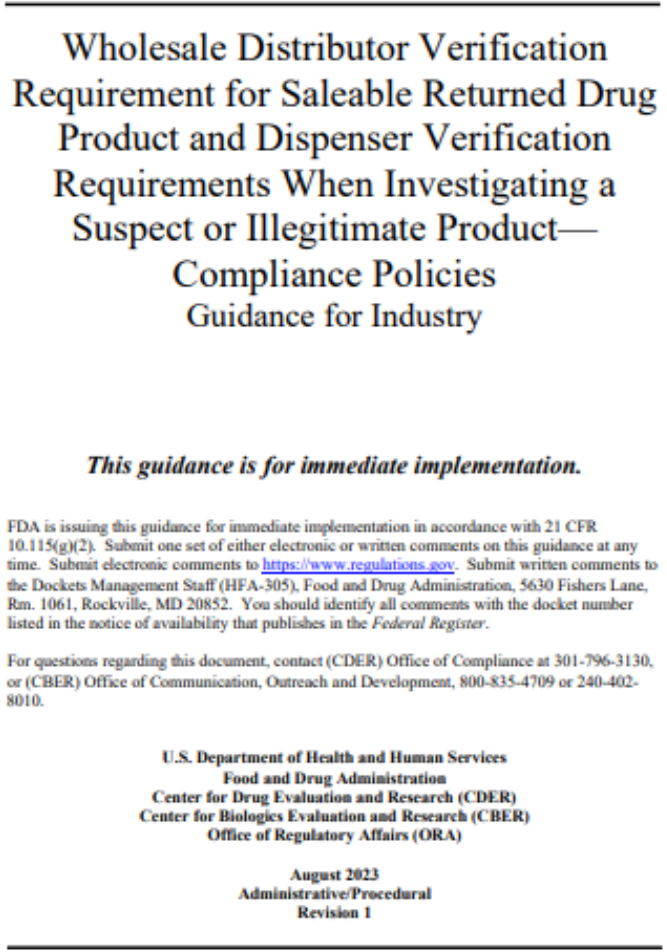
- Enhanced Product Tracing
  - Individual PI must be in the TI
  - Selling trading partner should reconcile TI with product
  - Buying trading partner should match TI and TS with product
  - Data and product discrepancies and how to resolve them



- Systems and processes to respond to request for TI/TS from regulator

vs.

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



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

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

U.S. Department of Health and Human Services
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Center for Biologics Evaluation and Research (CBER)
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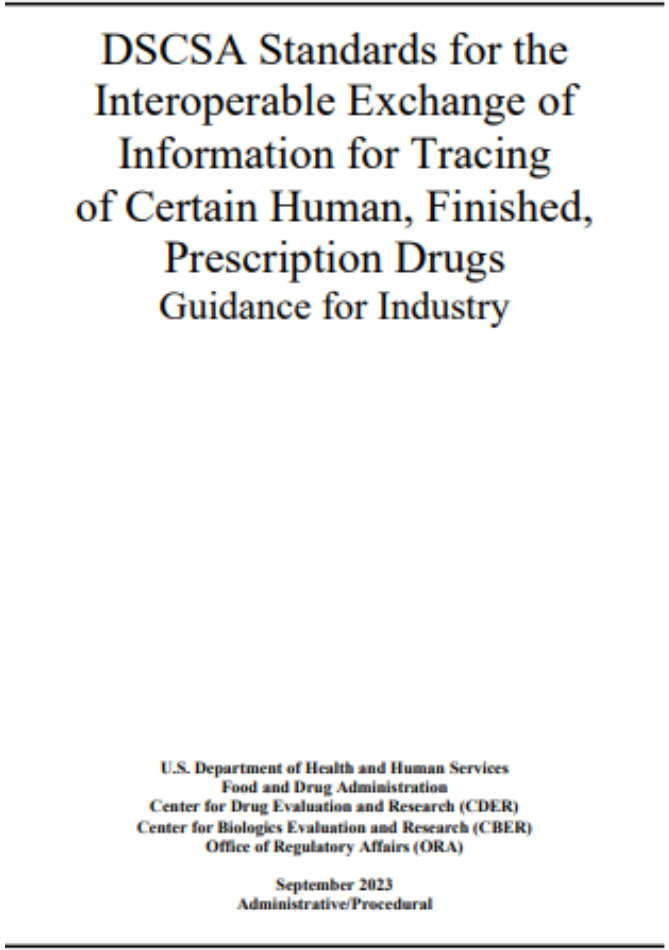
Administrative/Procedural
Revision 1

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



- Defines interoperability under EDDS
- Recommended usage of EPCIS standard
  - Key takeaway for pharmacies: Importance of GLN, ATP

Future Considerations

Industry Seeking Phased Implementation

Small Dispenser Assessment RFC

- Request for Comment published Aug. 10
  - Comments due Sept. 11
- 25 or fewer FTEs
- Readiness for Nov. 27, 2023 deadline re: software and hardware

Ongoing Concerns

- Trading partner readiness issues
- What does the EDDS FDA enforcement discretion mean?
  - Liability risks remain
- 3Ts and misbranded drugs
- 340B
- Enforcement, especially non-FDA enforcement
- Proposed rule on wholesaler and 3PL licensing standards

Assessment Answer #1

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Assessment Answer #2

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A. True

B. False

Questions?

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