Drug Supply Chain Security Act (DSCSA)
Public Meeting Series

Enhanced Drug Distribution Security

February 28, 2018

White Oak Campus

Silver Spring, MD

Enhanced Drug Distribution Security Goals – 2023

Package level interoperable, electronic tracing of products in November 2023 is expected to provide:

- Electronic exchange of transaction information for each sale of certain prescription drugs
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products when found
- Improved efficiency of recalls

FDA DSCSA Public Meeting Series

Stakeholder input on strategies and issues related to the enhanced drug distribution security provisions of the DSCSA

3 public meetings

Dates	Topics
August 23, 2017	• Supply chain security in 2023 • Enhanced drug distribution security needs
December 5-6, 2017	• Electronic interoperability • Standards for data exchange • Data architecture • Aggregation and inference
February 28, 2018	• Further refinement of enhanced drug distribution security needs • Building capacity for a unit-level system

Vision of the 2023 enhanced drug distribution system

- Provide increased public health benefits
- Ensure diligence and vigilance by all trading partners
- Support FDA's compliance and enforcement efforts
- Be adaptable and flexible
- Longer term…Be compatible with the health care system and global marketplace

Recap of December 2017 Meeting

- Addressed **standards for data exchange** issues and if there are other areas in need of standards
- Heard from outside speakers on **data architecture** and discussed how a distributed data architecture model can enable interoperability
- Learned about Europe's experience with the **Falsified Medicines Directive** from a European Union representative
- Held supply chain sector breakout sessions on **aggregation and inference** needs and practices
- Held breakout sessions that addressed different **scenarios** related to data exchange that may present challenges to industry.

Goals of the Meeting

- This is the third in a series of public meetings that will provide members of the pharmaceutical distribution supply chain and other interested stakeholders an opportunity to discuss strategies and issues related to the enhanced drug distribution security provisions of the DSCSA.
- FDA would like to obtain input from stakeholders about:
  - Enhanced drug distribution security
  - Verification using the product identifier
  - Guardrails identification and prioritization
- The information gathered from the meeting and comments in the public docket will further inform FDA's development of the enhanced drug distribution security provisions of the DSCSA.

FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
February 28, 2018

Agenda

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Welcome and Opening Remarks	Dr. Scott Gottlieb FDA Commissioner
9:15 – 9:30 am	Goals of the Public Meeting and Meeting Logistics	Ilisa Bernstein FDA/Center for Drug Evaluation and Research (CDER)
9:30 – 10:10 am	Enhanced Drug Distribution Security Needs • *Large Group Discussion*	Connie Jung FDA/CDER
10:10 – 10:30 am	Confidential Commercial Information and Trade Secrets	Howard Philips FDA/CDER
10:30 – 10:45 am	Break	
10:45 – 12:00 pm	Verification of the Product Identifier • *Supply Chain Sector Breakout Session* • *Large Group Discussion*	Ilisa Bernstein FDA/CDER
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	Guardrails: Identification and Prioritization • *Breakout Session*	Daniel Bellingham FDA/CDER
2:30 – 2:45 pm	Break	
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3:45 – 4:00 pm	Next Steps/Closing Remarks	Ilisa Bernstein FDA/CDER
4:00 pm	Adjourn	

Meeting Logistics

- Housekeeping (pre-order lunch, restrooms)
- Participants have been assigned to specific groups to ensure representation of different trading partner and stakeholders.
- Breakout Sessions:
  - Sessions will involve smaller group discussions; Group assignments are on your badge.
  - Each group will have FDA representatives as a facilitator and a scribe to aid the discussion and capture participant input.

Group 1	Group 2	Breakout Session in:
Group A	1-4	Great Room
Group B	5	Room 1406
Group C	6	Room 1408

- Information captured will be aggregated and not associated with a specific individual or company.
- Press/Media representative(s) may be in attendance and have a separate assigned table.
- The Concepts and Terminology document is provided to help facilitate discussions at these public meetings and should not be interpreted as legal or regulatory definitions or guidance.

Enhanced Drug Distribution Security Needs

1. Fully electronic and interoperable
2. Secures data & system(s) against falsification, malicious attacks, & breaches
3. Ensures protection of confidential commercial information & trade secrets
4. Enables authorized trading partners to exchange & store data accurately and efficiently for each transaction
5. Enables authorized trading partners to promptly respond to a request for product tracing information
6. Enables prompt gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer when appropriately requested
7. Enables authorized trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns
8. Signals that a product has been determined to be illegitimate (e.g., red flags)
9. Enables scalability for integration by any size business
10. Prevents entities who are not “authorized” from accessing & using the system

Enhanced Drug Distribution Security Group Discussion

- Are there other enhanced drug distribution security needs that have not been identified that would help trading partners, FDA, and other members of the supply chain?
- Are all of these elements required as of “day one” in 2023 or are there some that might be phased in? If so, what’s needed first and what can come later?
- Are there other stakeholders that need to be involved besides trading partners, solution providers, FDA, other Fed/State, standards organizations?

FDA's Protection of Confidential Information

FDA/CDER/Division of Information Disclosure Policy (DIDP)

- Disclosure of CDER records is handled by DIDP.
- DIDP processes and responds to requests made pursuant to the Freedom of Information Act ("FOIA") for documents in the possession of CDER.
- DIDP is also responsible for proactively reviewing, redacting, and posting on FDA's website, drug approval packages and CDER-issued warning letters.
- DIDP responds to requests for CDER documents made by the U.S. Congress, foreign, state, and local governments, and other federal agencies, and by third-party subpoenas and court orders.

Freedom of Information Act (FOIA) Access to Records

- Any person has a right, enforceable in court, to obtain access to federal agency records except to the extent that the records (or portions of them) are protected from disclosure

What Laws Affect Disclosure?

- In addition to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, the following disclosure laws are used at CDER:
  - Trade Secrets Act (TSA), 18 U.S.C. § 1905
  - Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*
  - Privacy Act, 5 U.S.C. § 552a
  - Others (e.g., Ethics in Government Act)

What FDA Regulations Affect Disclosure?

- FDA Regulations—have the "force and effect of law"
- CDER's disclosure activities are governed primarily by 21 C.F.R.
  - Part 20: Public Information
  - Part 21: Privacy Act
  - Part 300: Human Drugs
    - § 312.130: Public disclosure of INDs
    - § 314.430: Public disclosure of NDAs and ANDAs
  - Part 600: Biologics
    - § § 601.50 & 601.51: Public disclosure of INDs and BLAs

FOIA – The Exemptions

- Congress included nine exemptions in the FOIA in order to protect certain information from disclosure.
  - Exemption 1.--Classified documents
  - Exemption 2.--Internal personnel rules and practices
  - Exemption 3.--Information exempt under other laws
  - *Exemption 4.--Confidential business information*
  - *Exemption 5.--Internal Government communications*
  - *Exemption 6.--Personal privacy*
  - *Exemption 7.--Law enforcement*
  - Exemption 8.--Financial institutions
  - Exemption 9.--Geological information

  * 4 out of the 9 exemptions are routinely used by CDER

FOIA: What is an agency record?

- Record that
  - is either created or obtained by an agency, and
  - is under agency control at the time of a FOIA request.
- Includes more than "paper" records:
  - Electronic media (e.g., email, computer databases, computer software)
  - Videotapes, photos, audiotapes
  - DSCSA records can be paper or electronic

FOIA Exemption (b)(4)

Trade Secrets

and

Confidential Commercial Information

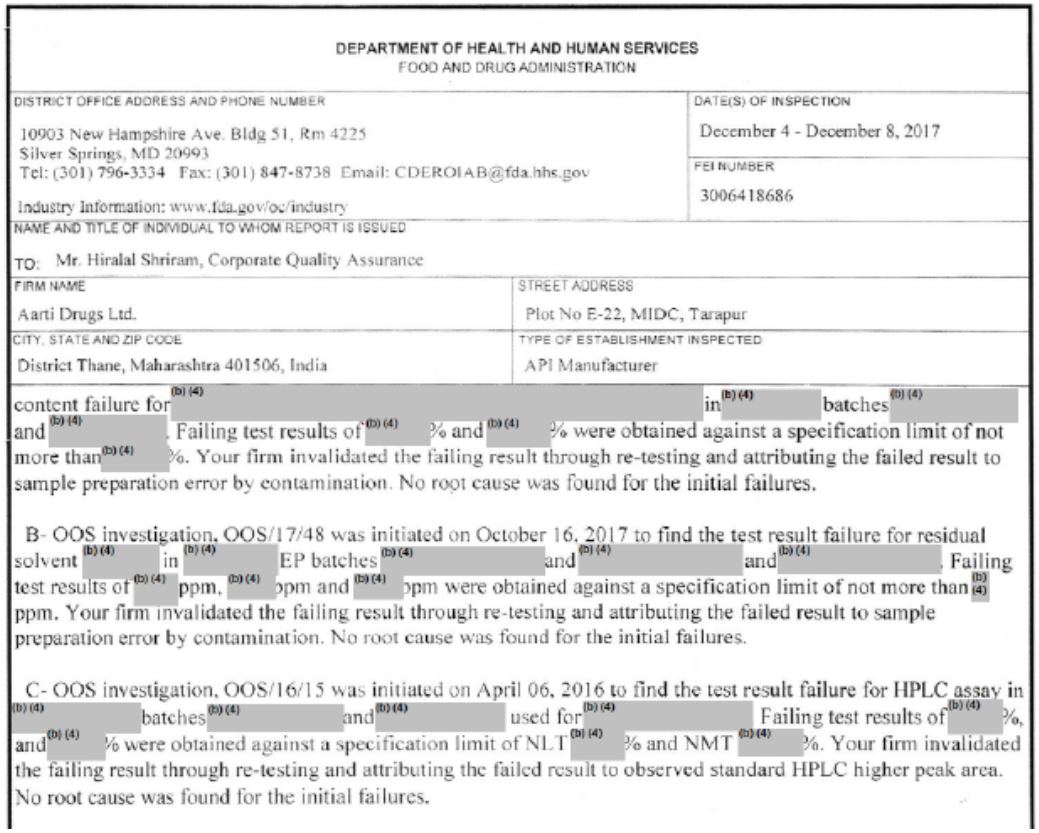
FOIA Exemption (b)(4)

- Allows agencies to withhold:
- “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”

Confidential Commercial Information

- Examples (if not made public by owner):
  - Sales volume
  - Customer and supplier names
  - Contractor and consultant names
  - Business plans

Example of FDA Protecting Confidential Information



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave. Bldg 51, Rm 4225 Silver Springs, MD 20993 Tel: (301) 796-3334 Fax: (301) 847-8738 Email: CDEROIAB@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	December 4 - December 8, 2017
	FEI NUMBER 3006418686

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Hiralal Shriram, Corporate Quality Assurance

FIRM NAME	STREET ADDRESS
Aarti Drugs Ltd.	Plot No E-22, MIDC, Tarapur
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
District Thane, Maharashtra 401506, India	API Manufacturer

content failure for [redacted] in [redacted] batches [redacted] and [redacted]. Failing test results of [redacted]% and [redacted]% were obtained against a specification limit of not more than [redacted]%. Your firm invalidated the failing result through re-testing and attributing the failed result to sample preparation error by contamination. No root cause was found for the initial failures.

B- OOS investigation, OOS/17/48 was initiated on October 16, 2017 to find the test result failure for residual solvent [redacted] in [redacted] EP batches [redacted] and [redacted] and [redacted]. Failing test results of [redacted] ppm, [redacted] ppm and [redacted] ppm were obtained against a specification limit of not more than [redacted] ppm. Your firm invalidated the failing result through re-testing and attributing the failed result to sample preparation error by contamination. No root cause was found for the initial failures.

C- OOS investigation, OOS/16/15 was initiated on April 06, 2016 to find the test result failure for HPLC assay in [redacted] batches [redacted] and [redacted] used for [redacted]. Failing test results of [redacted]%, and [redacted]% were obtained against a specification limit of NLT [redacted]% and NMT [redacted]%. Your firm invalidated the failing result through re-testing and attributing the failed result to observed standard HPLC higher peak area. No root cause was found for the initial failures.

For discussion purposes only. Developed for use at this public meeting. This information should not be interpreted as a final decision or position of FDA.

Limited Exceptions

- Court order
- Congress
- Administrative or court enforcement actions (limited to information necessary to effectuate such action (21 CFR 20.91)

--- FDA will always try to limit disclosure as much as possible---

PROTECTING INFORMATION IS IMPORTANT TO FDA

- FDA must comply with the laws and regulations requiring it to protect the information in its possession.
- FDA has been protecting information under the Freedom of Information Act since the law was enacted over 50 years ago.
- FDA has confidential information from industry, patients, other federal agencies, foreign regulators, etc., and understands the need to protect it.

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Verification of the Product Identifier

Definition of "verify or verification" [section 581(28) of the FD&C Act]

…determine whether the product identifier affixed to or imprinted upon, a package or homogenous case corresponds to the SNI or lot number and expiration date assigned to the product by the manufacturer or repackager, as applicable…

Requirements:

- Current
- After 11/27/2018
- Enhanced verification in 2023

Why is this important?

- Checks authenticity of product that you have
- Indicates whether the product should be in the supply chain
- Identifies the product identifier associated with an illegitimate product (i.e., "red flags" in the supply chain)

Breakout Session
Verification of the Product Identifier

- What do you expect will be some of the challenges with your sector's ability to verify product identifiers accurately and efficiently?
- What are the necessary procedures that are being taken to solve these challenges?
- How do you anticipate verification being done in 2023?
- What lessons can be learned for 2023 from your sector’s preparation for the verification requirement for saleable returns?

Breakout Session
Verification of the Product Identifier

Manufacturer/Repackager

In preparation for enhanced drug distribution security in 2023:

- What systems and processes have you implemented or plan to implement for responding to:
  - Trading partner request for verification at the package level
  - Trading partner request for verification of saleable returns at the package level
- Will you change your current systems or processes for notifications of high-risk or illegitimate products?
- How will you confirm that the verification request comes from an authorized trading partner that received your product?
- Have you identified any readability issues for the human readable or machine readable formats of the product identifier? If so, how are you dealing with these issues?

Breakout Session
Verification of the Product Identifier

Wholesale Distributors

In preparation for enhanced drug distribution security in 2023:

- What systems and processes have you implemented or plan to implement for responding to:
  - Trading partner request for verification at the package level
  - Trading partner request for verification of saleable returns at the package level
- Will you change your current systems or processes for notifications of illegitimate product?
- How would the practice of inference affect your ability to verify product?
- How will you confirm that the verification request comes from an authorized trading partner that received your product?
- Have you identified any readability issues for the human readable or machine readable formats of the product identifier? If so, how are you dealing with these issues?

Breakout Session
Verification of the Product Identifier

Dispensers

In preparation for enhanced drug distribution security in 2023:

- What systems and processes have you implemented or plan to implement for:
  - Responding to request for information from FDA (or other Federal/State official)
  - Making requests for verification
- How would the practice of inference affect your ability to verify product?
- Will you change your current systems or processes for notifications of illegitimate product?
- Have you identified any readability issues for the human readable or machine readable formats of the product identifier? If so, how are you dealing with these issues?

Breakout Session
Verification of the Product Identifier

Meeting participants will be divided by supply chain sector:

- Mostly manufacturers will be in Group A
- Mostly wholesale distributors will be in Group B
- Mostly dispensers (pharmacies) will be in Group C
- Other stakeholders will be mixed in either Group A, B, or C

Group	Breakout Session in:
A	Great Room
B	Room 1406
C	Room 1408

Guardrails: Identification and Prioritization

- Supply chain stakeholders have expressed a need for “guardrails” to assist in the development of enhanced drug distribution security by 2023.
- For today’s discussion, guardrails are issues where stakeholders would like further clarification from FDA.
- Examples of these types of issues that we have heard from stakeholders include:
  - Inference
  - Aggregation issues
  - Governance
  - Master data
  - Data architecture
- Goals for this session:
  - Expand the discussion on potential guardrails
  - Prioritize the topics/issues for which guardrails would be helpful based on the level of importance and need by stakeholders

Breakout Session
Guardrails: Identification and Prioritization

- What topics/issues do you believe guardrails would be helpful to assist with the development of enhanced drug distribution security by 2023?
- What are the other areas you think clarification is needed for industry to adequately prepare for implementation of the 2023 requirements?
- Please prioritize the most important topics/issues that need guardrails to ensure the successful implementation of the 2023 system.

Breakout Session
Guardrails: Identification and Prioritization

Meeting participants will be divided in groups that represent a variety of supply chain stakeholders.

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How to submit comments to the docket

- Submit electronic comments to http://www.regulations.gov
- Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- All comments should be identified with the docket number FDA-2017-N-3857.
- Please note that the deadlines for submitting either electronic or written comments are 30 days after the meeting to which the comments relate.
- Stakeholder input essential and valued!