Developing a System for Track and Trace and Authentication for Prescription Drugs

FDA Track and Trace Public Workshop

February 15-16, 2011

FDA Public Workshop: Determination of System Attributes for Tracking and Tracing of Prescription Drugs

- Welcome
- Review of System Goals, Attributes, Terminology
- What we heard so far (Session 1 & 2 Outputs)
- Logistics for today
- Session 3 – Data Management
- Session 4 – Workshop Outputs

System Goals and Attributes

Goals:

1. Preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
2. Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
3. Providing accountability for the movement of drugs by supply chain participants
4. Improving efficiency and effectiveness of recalls

Potential System Attributes:

- Capable of capturing the unique identification of a product and status of the number
- Ensure interoperability to enable supply chain participants to securely capture, store, and exchange track-and-trace data accurately and efficiently
- Authenticates the standardized numerical identifier (SNI) and entire distribution history of each package
- Enable appropriate access to track-and-trace data necessary to achieve system goals
- Ensure security of data and systems from falsification, malicious attacks, and breaches
- Ensure confidential commercial information is protected
- Ensure applicable patient privacy is maintained

Key Concepts & Terminology (1)

Serialization	• Process of uniquely identifying a product • FDA issue recommendations in the Standard Numerical Identifier (SNI) Guidance, March 2010
Package (Drug package)	• "…the prescription drug package [is] the smallest unit placed into interstate commerce by the manufacturer or the repackager that is intended by that manufacturer or repackager, as applicable, for individual sale to the pharmacy or other dispenser of the drug product. Evidence that a unit is intended for individual sale, and thus constitutes a separate "package" for purposes of this guidance, would include the package being accompanied by labeling intended to be sufficient to permit its individual distribution…" (FDA SNI Guidance)
Interoperability	• establishes compatible data and process standards to enable system participants to have the capability of sharing data by integrating into the same system
Authentication	• verifying that an SNI is a valid number for the package with which it is associated. It also involves verifying that the package was sold, purchased, traded, delivered, handled, stored, brokered by, or otherwise transferred from legitimate supply chain participants, and confirming that there are no discrepancies in the distribution history.
Data Management	• provides standardized mechanisms that supply chain participants use to capture, store, protect, and utilize track-and-trace data to facilitate authentication and interoperability. These mechanisms may include information for ensuring compliance of and accountability for established processes, as well as corrective action if these processes are not followed.

Key Concepts & Terminology (2)

Track-and-trace data	• Any information collected about each package from the point of manufacture to the point of dispense or destruction
Pedigree	• Distribution history of a drug package
Accountability	• When a person or entity has to report, explain, justify, or be responsible for effectively takes custody or ownership of a package
Status	• The description of the disposition of the package as it moves through the supply chain (e.g., recall in process, in transit, destroyed, dispense, stolen, etc.)
Attribute	• Properties or capabilities of the system that would allow it to meet at least one of the stated system goals
Centralized System	• System where data from all stakeholders is stored in one central database
Decentralized System	• System where data is stored across multiple databases

A sample of what we heard from yesterday's sessions upon initial review (not a comprehensive list; full summary will be posted after the workshop)

Major themes we heard from you

- Desire for national standards to help guide track and trace; avoid different, state standards
- Desire to use established standards where applicable rather than creating new ones
- Strong recommendations for staged implementation (different views on how best to implement, but agreement that system should be phased in)
- Several groups discussed pilot programs in order to work out difficulties prior to any full rollout
- Need for FDA to be explicit and detailed in defining system goals and functional standards
- Clear guidance on minimum standards and what participants will be required to do – recommendation for FDA to focus on functional standards, not specific technologies
- Player validation is a critical concern, as there may be gaps in existing processes of how players are licensed across different states
- Currently have fragmented authority for supply chain participants - need to have a consistent national database for track & trace
- System requirements may result in significant changes to existing business and operational processes
- Other significant changes such as system integration, staff training, and inventory handling need to be considered

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Session 3

DATA MANAGEMENT

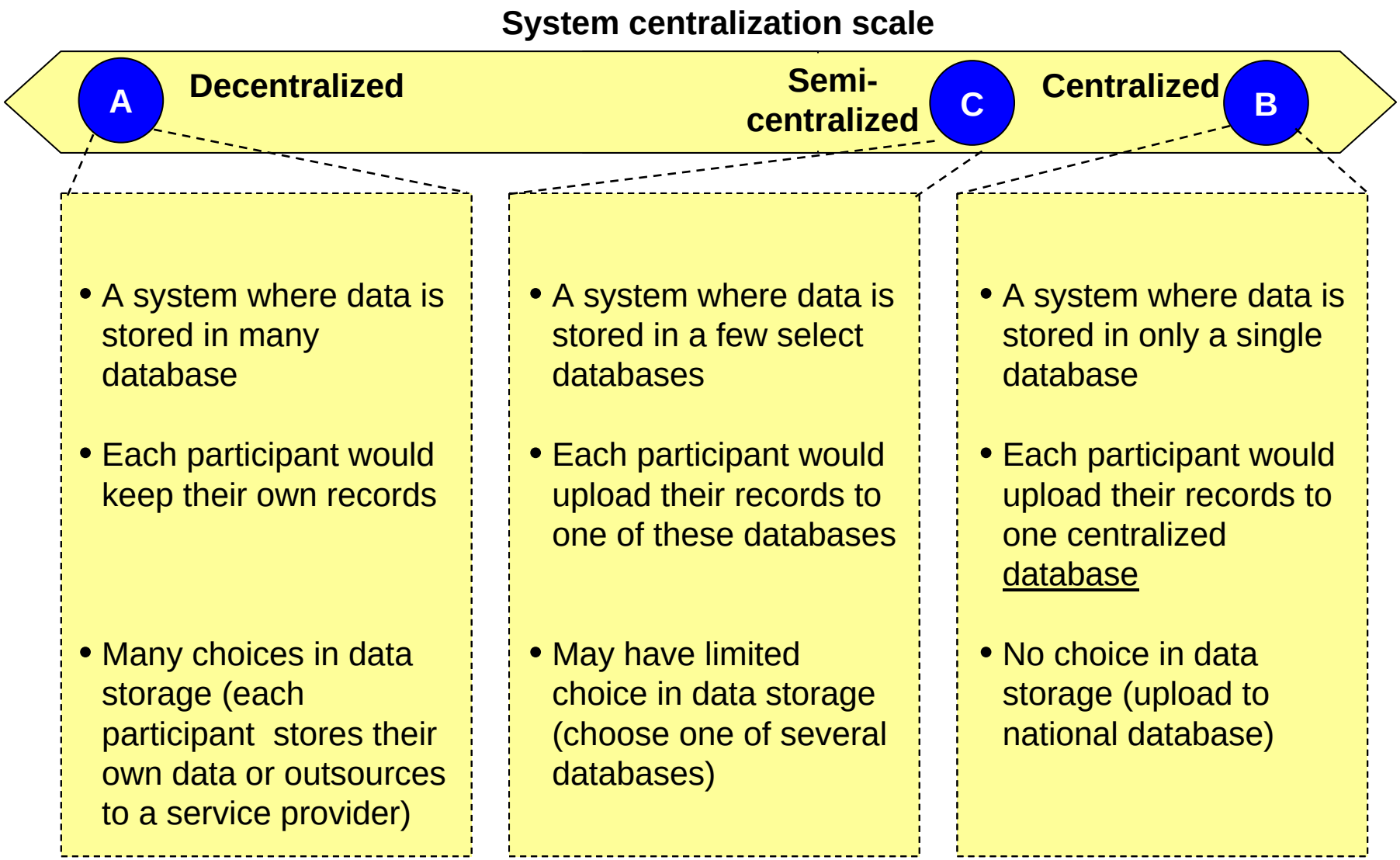
Terminology: What is data management?

Data management provides standardized mechanisms that supply chain participants use to capture, store, protect, and utilize track-and-trace data to facilitate authentication and interoperability. These mechanisms may include information for ensuring compliance of and accountability for established processes, as well as corrective action if these processes are not followed.

Specifically, data management includes:

- Determining where and how data should be stored;
- Identifying and upholding procedures that protect and secure data;
- Defining and permitting access to participants' data in a secure, confidential manner; and
- Determining accountability and corrective action in certain circumstances (e.g., compliance)

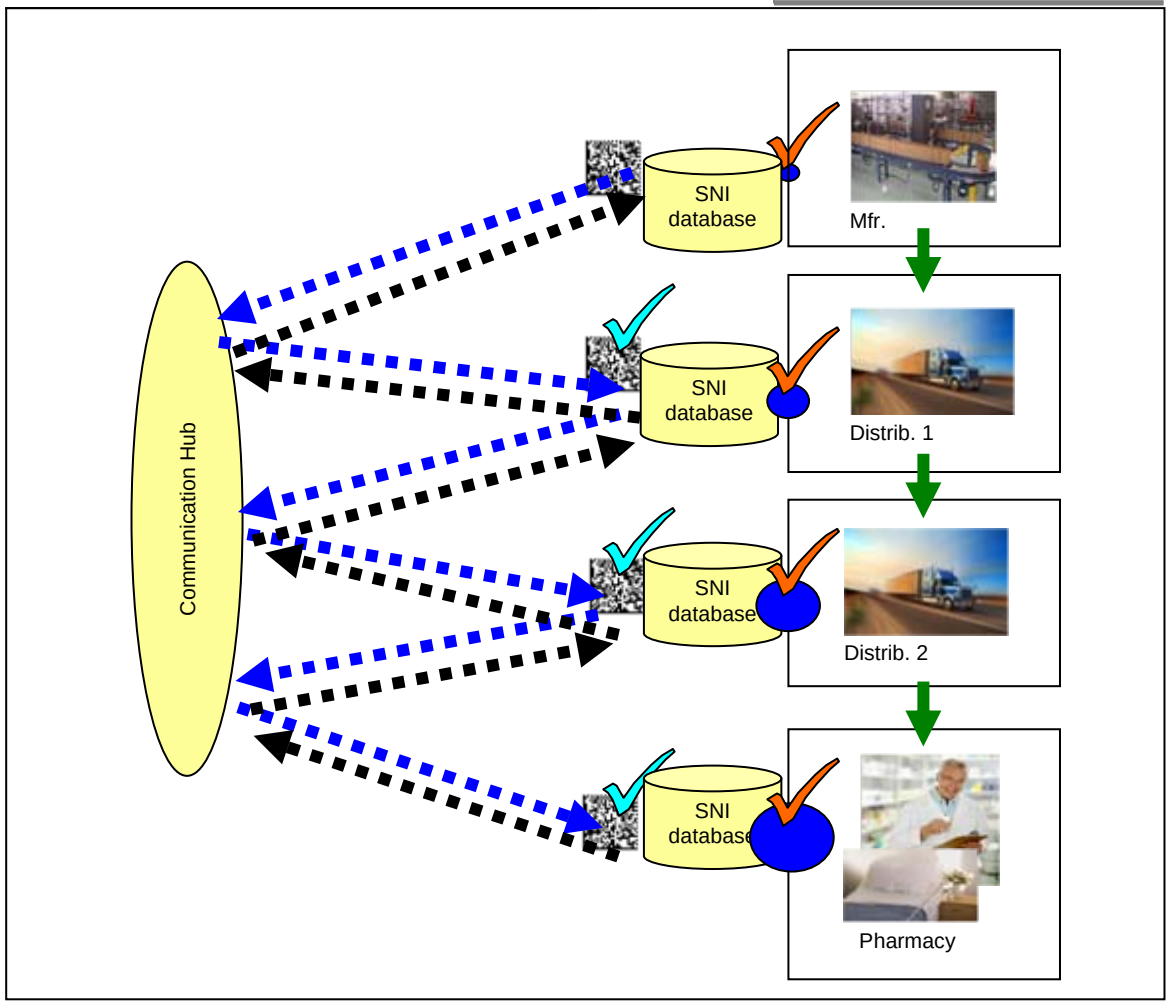
Overview of system options



A Decentralized system option

Decentralized Model

ILLUSTRATIVE EXAMPLE



Movement of Goods

Authentication of SNI

Authentication of Distribution History

Verify SNI

Verify distrib. history

oint of failure –
on doesn't shut down for
hen one database crashes

pedigree

siness intelligence by letting
pant keep their own data

practices may change for
nts (e.g. scanning)

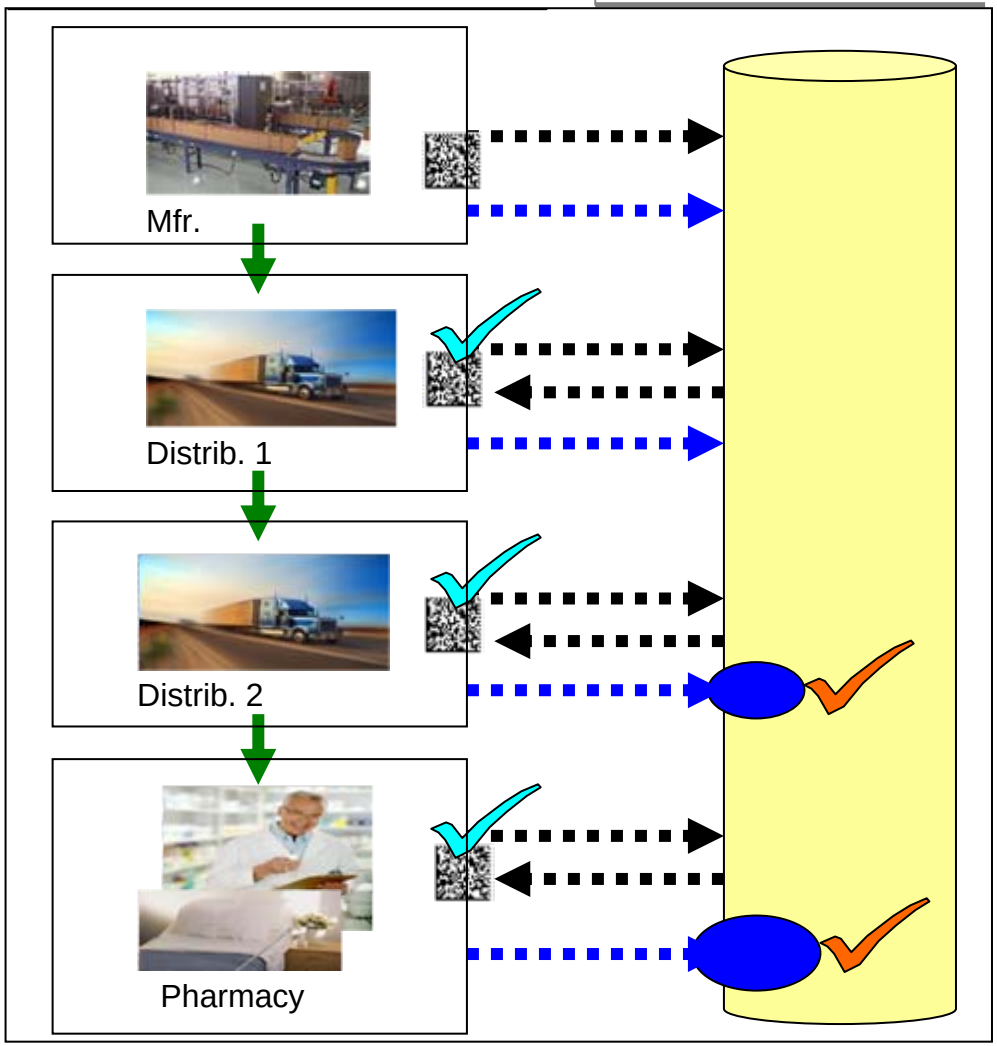
igh investment in database
curity technology

ystems like this exists given
e complexity of this model

B Centralized system option

Centralized Model

ILLUSTRATIVE EXAMPLE



Movement of Goods

Authentication of SNI

Authentication of Distribution History

Verify SNI

Verify distrib. history

Pros

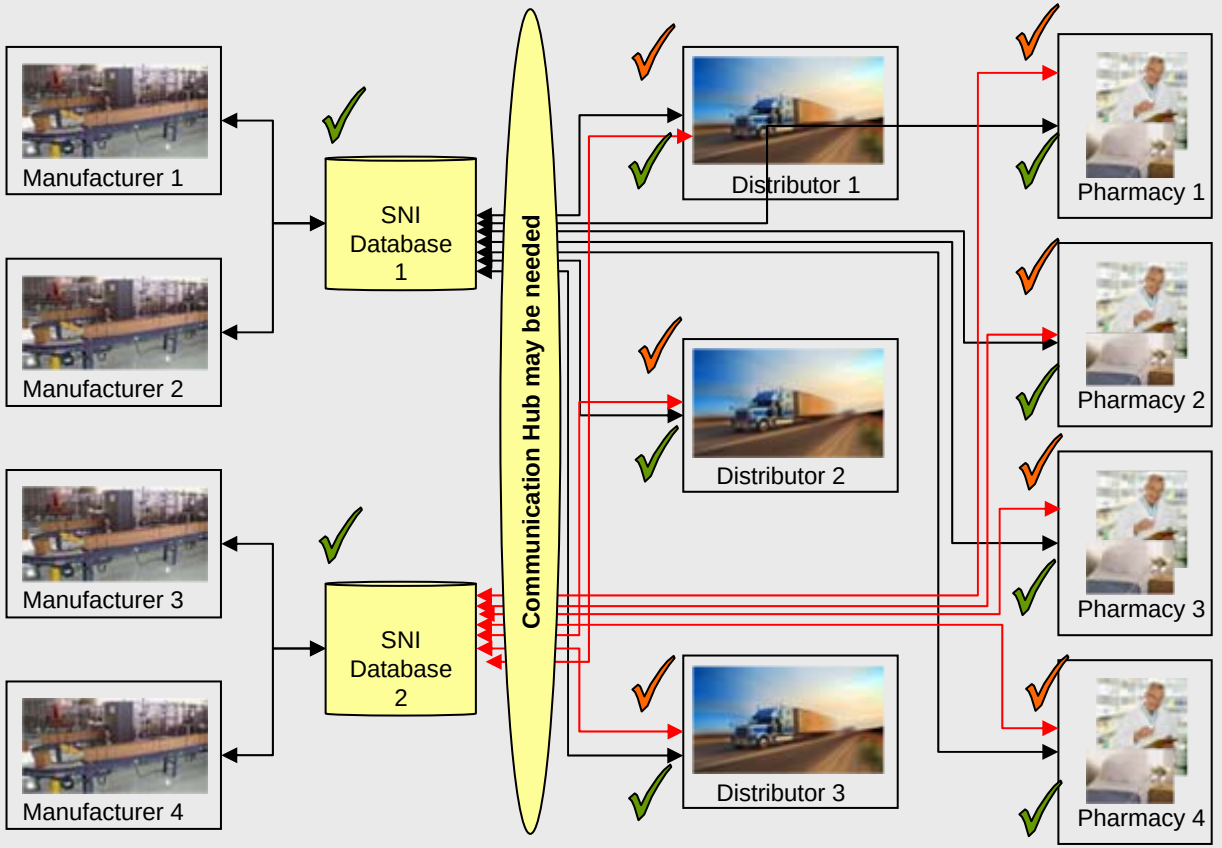
- Increases interoperability by using a single format
- Enables full and rapid pedigree – every record is in one place
- Potentially easier to see fraudulence, given all records in one place

Cons

- Single point of failure – authentication will shut down for everyone if the database crashes
- Creates an unprecedented amount of data that will need to be expertly managed and stored
- Centralized body would need tobe formed and operational procedures defined
- Business intelligence submitted by each participant would be stored in the same database – would need good security

C Semi-centralized system option

ILLUSTRATIVE EXAMPLE



✓ Verification of SNI

✓ Verification of distribution history

Pros

- Introduces options for companies of where to store their data; may lead to competitive service and pricing
- Enables interoperability by using one data format and communication across several main databases
- Enables full and rapid pedigree – all records for SNI are in one database

Cons

- Creates a large amount of data that should be expertly managed and stored
- Business intelligence submitted by each participant would be stored in the same database – would need good security

Breakout discussion questions: Data management

- Which option - decentralized, fully centralized, or semi-centralized - would be most feasible for industry to implement while accomplishing the goals of a track and trace system?
- Who is best suited to build and maintain the database(s) necessary for track & trace?
- What rules or standards should be in place regarding access and utilization of track & trace data?
- How can data security be achieved?

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Session 4

WORKSHOP OUTPUTS

What we need from you

- **Track-and-trace may be a transformational industry change**
  - We want to hear your input
- **Track-and-trace may necessitate significant changes in business activities**
  - We want to understand the specific impact of these standards on your business practices and finances
- **Track-and-trace has been implemented differently in other industries and countries**
  - We want to know what timeline and approach might work

Breakout discussion questions: Workshop output

- How do you envision a track and trace system working successfully?
- What can be done to help faster acceptance and implementation?
- What would be a reasonable timeframe to phase in a track-and-trace system? What should rollout strategy look like? (e.g., manufacturer first, etc.)
- What are your top 3 concerns about track-and-trace?
- What additional factors must be considered that we have not discussed today?

System Goals and Attributes

Goals of a track and trace system for prescription drugs (including biologics) include

1. Preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
2. Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
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Potential System Attributes

- Capable of capturing the unique identification of a product and the status of the product
- Ensure interoperability to enable supply chain participants to securely capture, store, and exchange track-and-trace data accurately and efficiently
- Authenticate the unique identifier (standardized numerical identifier or SNI) and entire distribution history of each package
- Enable appropriate access to track-and-trace data necessary to achieve system goals
- Ensure security of data and systems from falsification, malicious attacks, and breaches
- Ensure confidential commercial information is protected
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Source: FDA working team discussions

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THANK YOU FOR YOUR PARTICIPATION!