Proposed Pilot Project(s) Under the Drug Supply Chain Security Act

Day 1

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-2016-N-0407.
- Public workshop docket will close on April 21, 2016.
- Stakeholder input essential and valued!

  (Early submissions appreciated)

- *Public workshop webpage:*
  http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm

Workshop Logistics

- This workshop is designed to be collaborative and solution-focused.
- Participants have been assigned to specific tables to ensure representation of different trading partner and stakeholder groups.
- As such, please remain at your assigned table.
- Over the next two days, you and your group are going to work together to discuss ideas that will inform the development of pilot projects to enhance the safety and security of the pharmaceutical distribution supply chain.
- Each table will have FDA representatives as a facilitator and scribe to aid the discussion and capture participant input.
- Information captured will be aggregated and not associated with a specific individual or company.
- Press/Media representatives are in attendance to cover the workshop and have a separate assigned table.

Discussion Tips

Think 'outside the box'
Consider different approaches

- **No complaining**
- **Be solution-focused**

Don't disregard an idea

- Initially consider all ideas as good ideas
- Build on someone's idea to make it better

Evaluate ideas *after* brainstorming

- **Be engaged**
- **Be open to others' opinions and ideas**
- **Add your thoughts – each perspective is important**
- **Focus on a workable solution**
- **Ideas should not be product- or service-specific**

FDA Public Workshop
April 5-6, 2016
Proposed Pilot Project(s) under the Drug Supply Chain Security Act

Agenda

DAY 1	Tuesday, April 5, 2016	Speaker/Moderator
8:30 – 9:00 am	Registration/Check-in*	
9:00 – 9:15 am	Welcome and Opening Remarks	Ilisa Bernstein
9:15 – 10:15 am	Workshop Logistics Goals of the Workshop	Connie Jung
10:15 – 10:30 am	Break	
10:30 am – 12:00 pm	Session 1 – Proposed Pilot Project Objectives	Dan Bellingham
12:00 – 1:15 pm	Lunch	
1:15 – 1:45 pm	Session 1 – Proposed Pilot Project Objectives (cont.)	
1:45 – 2:15 pm	Reports on Session 1	
2:15 – 3:15 pm	Group Discussion and Summary	Robert Celeste (FDA Contractor)
3:15 – 3:30 pm	Break	
3:30 – 4:55 pm	Group Discussion and Summary (cont.)	
4:55 - 5:00 pm	Plan for Day 2/Adjourn	Connie Jung

DAY 2	Wednesday, April 6, 2016	Speaker/Moderator
8:30 – 9:00 am	Registration/Check-in*	
9:00 – 9:10 am	Welcome	Kate Bent
9:10 – 9:20 am	Recap of Pilot Project Objectives	David Markert
9:20 – 10:20 am	Session 2 - Evaluation Methods	Bobby Chun
10:20 – 10:35 am	Break	
10:35 am – 12:00 pm	Group Discussion - Evaluation Methods	Connie Jung
12:00 – 12:15 pm	Closing Remarks	Ilisa Bernstein
12:15 pm	Adjourn	

Purpose of the Public Workshop

- This public workshop will provide a forum for discussing proposed design objectives of pilot projects that will explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.
- FDA would like to obtain information and input from interested pharmaceutical distribution supply chain members about issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying the system attributes that are necessary to implement the requirements established under the DSCSA.
- The information gathered from the workshop and the public comments submitted to the docket will further inform FDA's development of its pilot project program.

Relevant provisions of the DSCSA for today's workshop

- Product tracing (package-level *by 2023*)
- Product verification of suspect and illegitimate product
  - Quarantine and investigation (steps for detection and response)
  - Notification, recordkeeping
- Product identification (*applied to product beginning 2017*)
- Authorized Trading Partners
- Enhanced system (*electronic, interoperable system to trace products at the package-level by 2023*)

Focus of FDA Pilot Project(s)

- Assess the ability of supply chain members to:
  - satisfy the requirements of section 582
  - to identify, manage, prevent the distribution of suspect and illegitimate drugs
- Identify the system attributes needed to accomplish the requirements of section 582 (particularly utilizing a product identifier for product tracing or verification)
- Demonstrate the electronic, interoperable exchange of product tracing information across the pharmaceutical distribution supply chain
- FDA will coordinate with stakeholders that reflect the diversity of the pharmaceutical distribution supply chain, including large and small entities from all industry sectors.

Goals of the Workshop

Day 1

- To obtain stakeholder input on objectives of pilot projects
- To discuss proposed pilot project objectives
  - Identify common themes
  - Consider trading partner size / capabilities
  - Identify challenges

Day 2

- To obtain stakeholder input on evaluation methods of pilot project objectives

Terminology

Aggregation	**Physical (packing):** The process of packaging a number of packages within outer layers of packaging (bundles, cases, totes, pallets, etc.) **Data:** Recording the hierarchical information related to packages and any other outer layers of packaging for shipment
Disaggregation	**Physical (unpacking):** The process of unpacking a number of packages from outer layers of packaging (bundles, cases, totes, pallets, etc.) **Data:** Recording the hierarchical information related to packages received and unpacked in a shipment

Terminology

Inference	Packages are deemed to be contained within outer levels of packaging (bundles, cases, totes, pallets, etc.) based on information that is provided by the seller
Interoperability	The ability to exchange product tracing information accurately, efficiently, and consistently among trading partners (reference: FDA Guidance, November 2014) (“electronic interoperability” would involve electronic formats, methods, or systems)

Terminology

System Attributes	System attributes are properties or capabilities of the system that are necessary to implement the requirements of section 582. The attributes of a product tracing system may include the following: • Capability to capture and maintain product tracing information • Interoperability to enable trading partners to securely exchange product tracing data accurately and efficiently • Capability to verify product • Controlled access to product tracing information by trading partners, FDA and other appropriate federal and state officials • Security of data and systems

Definitions in Section 581 of the FD&C Act

Product Identifier	a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product	Section 581(14)
Package	the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product	Section 581(11)(A)
Individual Saleable Unit	the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser	Section 581(11)(B)
Standardized Numerical Identifier	a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.	Section 581(20)
Verification or Verify	determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.	Section 581(28)

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SESSION 1
PROPOSED PILOT PROJECT OBJECTIVES

Pilot Projects - Design [Section 582(j)(2)(B)]

- utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;
- identify system attributes that are necessary to implement the requirements established under this section; and
- complete other activities as determined by the Secretary.

Session 1 - Discussion
Proposed Pilot Project Objectives

Overarching objectives:

Integration of the DSCSA's product-tracing requirements into daily operations (e.g., product sales, purchasing, and distribution)

Verification of suspect or illegitimate product (including the determination and handling

The ability of pharmaceutical distribution supply chain members to exchange product tracing information accurately, efficiently, and consistently among trading partners (e.g. interoperability)

Session 1 – Discussion
Example Scenarios

What are some example of practices, processes, and systems that should be piloted used to accomplish the requirements under section 582?

- Distribution/Logistics/Storage
- Manufacturing/Packaging/Labeling
- Errors/Inconsistencies
- Records/Record-keeping
- Other?

Session 1 – Discussion
Questions to Ask…

- Is this an important objective to be piloted?
- How might the objective be accomplished in a pilot?
- What are the challenges?
- How do you overcome the challenge(s)?

Session 1 – Considerations

Integration of the DSCSA's product-tracing requirements into daily operations (e.g., product sales, purchasing, and distribution)

- How are TI, TH & TS being provided, captured and maintained
- Are there scenarios that are more challenging than others
- How product identifiers on the product are captured
- How accuracy is maintained for aggregated data
- When it's appropriate to use inference

Verification of suspect or illegitimate product (including the determination and handling)

- How TI/TH/TS is utilized for verification
- Is the information easily retrievable/readily available
- How trading partners are notified of an Illegitimate product

The ability of pharmaceutical distribution supply chain members to exchange product tracing information accurately, efficiently, and consistently among trading partners (interoperability)

- What are some challenges with interoperability
- How to show successful interoperability amongst trading partners

GROUP DISCUSSION
PILOT PROJECT OBJECTIVES

Session 1 – Discussion
Questions to Ask…

- Is this an important objective to be piloted?
- How can it be accomplished in a pilot?
- What are the challenges?
- How do you overcome the challenge(s)?

Group Discussion

- Key pilot project objectives
- Pilot project challenges
- Suggestions to overcome challenges

Pilot Project Objectives Discussion Summary

- Highlights what we heard from participants during small and large group discussions
- This information should not be interpreted as a final decision or position of FDA
- Represents issues or activity to consider when formulating a pilot project
- Comments were grouped into:
  - **Pilot Project Design Considerations**
  - **Product Identifier Issues**
  - **Barcode Quality Issues**
  - **Interoperability**
  - **Data Issues**
  - **Database/Systems Issues**
  - **Business Processes (Aggregation, Verification, Notification, Exceptions Handling, etc.)**

Pilot project design considerations

- Ensure adequate mix of products and packaging levels represented
- Include all stakeholders (types and sizes) and different transactions
- Evaluate costs and benefits
- Flexibility of pilot projects (different partners, evolving scenarios, additional use cases)
- Risk-based approach to determine what to pilot (e.g., target known weaknesses in the supply chain)
- Include real life business processes
- Timing of pilots, to make them useful as trading partners implement requirements
- Human factors that could lead to challenges (errors, poor business practices)

Pilot project objectives (1)

- **Product Identifier Issues**
  - How serial numbers are issued & managed (including CMO's role if applicable)
  - Compare different standards for the identifier (10 or 11 digit NDC to be used in the SNI, 14-digit GTIN)
- **Bar Code Quality Issues**
  - Readability of bar code printed or affixed (environmental and human factors)
  - Convergence of linear and 2D barcodes on product – distinguishing which barcode to read/use and when
  - Determine minimum acceptable grade for bar code quality
  - Test various readers/scanner capabilities and variability
- **Interoperability**
  - Process and technical challenges due to variety of solutions expected
    - Central database vs. decentralized (peer-to-peer)
    - Trading partners with systems vs. others with little to no systems or using someone else's system
  - Maintaining visibility of the serialized product throughout the distribution supply chain
    - What to do when: a trading partner goes out of business or one acquires another business
    - Evaluate the use of EDI and EPCIS separately

Pilot project objectives (2)

- **Data Issues**
  - Use of technical standards for defining data attributes to enable interoperable transfers
  - Test methods to handle "master data" (product-specific data) vs. transaction data separately
    - Feasibility and acceptability of sending "master data" only once per shipment
    - Controlling "master data" to minimize redundancy
  - Integration into individual/company data systems
  - Evaluate data format or processes for data transfer
  - Performance measures (e.g., how to evaluate data from beginning to end of the product lifecycle, and vice versa, can you ascertain the actual change of ownership and transaction flows when examining data extracts)
  - Management of the system or data: use a consortium
  - Maintain data integrity/accuracy through distribution
  - Performance of the database when full or partially loaded with data
- **Database/System Issues**
  - Controlled/limited access to data by trading partners, FDA or other federal or state officials (data governance)
  - Status of product at all levels (each, case, pallet): e.g., expired, illegitimate, data error, associated decommissioned product identifier, other
  - Process for redaction of data (may not need to provide all data downstream)

Pilot project objectives (3)

- **Aggregation/Disaggregation**
  - Evaluate processes for product flow and data flow
  - Identify gaps in data or errors, accuracy of data, particularly downstream when searching or examining the data; how can errors be corrected
  - Impacts when inference is used vs. when inference is not used; impact on trading partners
  - When in distribution is inference no longer needed
  - Test multiple levels of adoption of inference, by different trading partners
- **Verification scenarios**
  - Using 2D barcode at the dispenser level (for verification or other purposes, determine training of personnel or equipment needed)
  - Process for investigation of suspect or illegitimate product (including all applicable trading partners), including testing boundaries of the system
- **Repackager Scenarios –** how to effectively and reliably link newly-issued product identifier back to original manufacturer product identifier
- **Special Scenarios –** data and product do not necessarily move together, which changes data governance and where data goes (ex. drop shipments, 340B, investigational drugs)

Pilot project objectives (4)

- **Notification scenarios**
  - Communication to brand owner when a suspect product is found or when illegitimate product is found and reported to FDA
  - Capabilities of the supply chain and data exchange mechanisms to achieve the statutory reporting timelines due to security, access to data, personnel availability
  - How to link or leverage notifications to patient
  - How to support forensic or lab analysis (up and down supply chain) when illegitimate product is confirmed
  - How do we ensure the current 'authorized partners' processes are in place and actually help to prevent illegitimate product from entering the supply chain
- **Exception Handling/Errors/Inconsistencies**
  - Focus on 'honest mistakes and errors' (includes aggregation error)
  - What triggers a suspect product or makes it non-saleable, vs. the 'honest errors'
  - Scenarios with "mixed product" (product along with other product that is subject to grandfathering, or that is subject to a waiver/exception/exemption)
  - Fixing over/under shipments (when more data is needed or more product is needed)

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Day 2

- To obtain stakeholder input on evaluation methods of pilot project objectives

Plan for Day 2

- Recap pilot project objectives identified and discussed on Day 1
- Discuss evaluation methods of pilot project objectives

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Public Workshop

April 5-6, 2016

See you tomorrow!