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

Day 2

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

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.

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

RECAP
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 – 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

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)?

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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SESSION 2
EVALUATION METHODS

Session 2 - Discussion
Pilot Project Evaluation

In general, evaluation factors will help provide:

- **Baseline measures:** To understand current practices and operations from the point of view of the pre-pilot process being examined.
- **Projections and insights:** To understand how the experience and observations might apply to other trading partner types or sizes or product types, in addition to the pilot project outcomes and differing results of similar pilot projects.
- **Scalability implications:** To understand how controlled, small scale versions of projected operations would change when increased in both the number of product or operations or in trading partner types and sizes.

Session 2 – Discussion Questions to Ask…

- How do we know if a pilot project has accomplished its objective?
- How can this objective be measured (qualitatively or quantitatively)?
- What do we expect to learn from this evaluation?
- How should the results of a pilot project be used?

Pilot Project Evaluation 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 metrics or methods to consider for evaluating certain pilot project objectives (quantitatively or qualitatively)
- Comments were grouped into:
  - **General Considerations**
  - **Interoperability**
  - **Data / Systems / Database Issues**
  - **Aggregation / Disaggregation**
  - **Verification / Notification**
  - **Exception Handling / Errors / Inconsistencies**

Pilot projects – General Considerations

- Metrics should focus on end-to-end supply chain and also specific operations
- Use initial pilots to identify other pilots based of severity or frequency of issue(s) encountered
- Simulate illegitimate products/transactions to test a process or system
- Document costs to implement, use, and maintain piloted solutions
- Document experience level of pilot partners – enables comparison of results from high and low experience partners
- Include special situations in pilot design (e.g., drop shipment, repackaging)
- Patient notification processes are out of scope of pilots
- Need clear definitions or standardization of product tracing data elements to effectively compare pilot results
- Need standards for location identification so we can share data with partners consistently (GLN, HIN, etc.)
- Need standardized rules for data redaction of product tracing information

For discussion purposes only. The content of this slide was identified during discussion sessions at this public workshop. This information should not be interpreted as a final decision or position of FDA.

Discussion Summary – Evaluation Methods (1)

- **Interoperability**
  - For both centralized and decentralized models; time implications
    - to investigate suspect and illegitimate products
    - for notifications required within the statutory timelines
    - for scalability – in regards to cycle times and ease of use when scaled up from pilot to full production
  - Product tracing information (across multiple partners)
    - capability to retrieve the information
    - time for retrieval or transfer of information
    - accuracy of the information (within and between systems)
  - Security and access
    - evaluate and document access levels for trading partners

Discussion Summary – Evaluation Methods (2)

- **Data / System / Database Issues**
  - System Performance and Effectiveness
    - Time to access and use product tracing information, once that data is received into a system
    - Quality of product tracing information
  - Operational Impacts
    - Data and product flow
      - Number of system interactions within one and amongst multiple trading partners
      - Time and resource changes on operations when data and product are not moving at same time (e.g., product arrives before data arrives)
    - Time for location/ownership/status changes to be reflected in the system
    - Product flow delays and associated costs due to system or data problems

Discussion Summary – Evaluation Methods (3)

- **Aggregation/Disaggregation**
  - Number of system and product interactions within one and amongst multiple trading partners
  - Time required to conduct aggregation/disaggregation operations and transactions
  - accuracy of aggregation data (measure error counts)
  - Time to gather aggregation/disaggregation data for investigations and notifications

Discussion Summary – Evaluation Methods (4)

- **Verification / Notification**
  - Response times: current vs. future process
  - Time needed to obtain product tracing information to respond to a request for verification
  - Time to gather product tracing information to support an investigation of a suspect or illegitimate product, or a recall
  - Percentage of items that are successfully verified vs. those that were targeted for verification

Discussion Summary – Evaluation Methods (5)

- **Exception Handling / Errors / Inconsistencies**
  - Measure percent errors detected: compare exceptions introduced vs. exceptions detected
    - Identify the first step in the process where error detected
  - Number of new or changed processes needed to accomplish DSCSA goals
    - Measure time and resource impacts
  - Honest Errors
    - Number of items unnecessarily quarantined or held-up
    - Measure time required to detect and correct errors
  - Measure barcode read error rates
    - Number of items unnecessarily quarantined or held-up
    - Measure time and resource impacts

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Thank you for your participation!