HDA
Healthcare Distribution Alliance

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RE: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act; Public Meeting; Request for Comments, 81 Fed. Reg. 64175 (Sept. 19, 2016), Dkt. No. FDA-2016-N-2673

Dear Doctor Bernstein, Doctor Jung, and Mr. Bellingham:

The Healthcare Distribution Alliance (HDA – formerly, the Healthcare Distribution Management Association) appreciates this opportunity to provide public comments to the Food and Drug Administration (FDA) regarding the Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act (DSCSA), 81 Fed. Reg. 64175 (September 19, 2016).

HDA represents the nation's primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned and small businesses. HDA member companies deliver nine million healthcare products to more than 200,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA participated in the public meeting FDA convened on October 14, 2016 regarding product identifier and other requirements of the DSCSA. Here, in response to FDA's request for comments, we address the following issues described further in the attached comment:

I. **The HDA Vision of the 2023 Interoperable, Electronic System**. For 2023 and beyond, the DSCSA creates an enhanced interoperable, electronic system where each authorized trading partner provides transaction information [TI] and a transaction statement [TS] to its customer, but not transaction history [TH]. If the customer, in turn, sells the product, it provides its own TI and TS to its subsequent customer, in each case with the TI reflecting *only* the current ownership and sale. HDA recommends that FDA express support for this interpretation to clarify and aid the development and implementation of a 2023 interoperable electronic system (or systems).

II. **Verification Requirements Within the DSCSA**. Trading partners must verify that a product's identifier corresponds to the standardized numerical identifier the manufacturer or repackager assigned to the product in two instances: (1) suspect product investigations and; (2) a wholesale distributor's or manufacturer's saleable returns. HDA urges FDA to resist any calls to impose verification requirements that are not supported by the DSCSA.

III. **Inference and Aggregation in the DSCSA**. Inference and aggregation are contemplated in the DSCSA and are essential to an efficient supply chain and continued provision of needed medicines to healthcare providers and patients. HDA asks that FDA support inference and aggregation in guidance.

IV. **Generic Pharmaceutical Association (GPhA) Request for a Delay of the 2019 Requirement to Verify Saleable Returns**. HDA is reluctant to endorse a delay as we believe that it will also delay the movement toward data and product identifier standardization necessary to achieve interoperability by 2023 as the DSCSA mandates. HDA suggests that FDA issue guidance supporting inference and aggregation so that systems have time to mature for those trading partners that can aggregate product and provide aggregated data in support of saleable returns verification. HDA also recommends that FDA support alternatives to use of inference and aggregation that allow for compliance with the DSCSA's requirements for verification of saleable returns effective in 2019 so that manufacturers and distributors can continue to efficiently and quickly meet the needs of healthcare professionals and patients.

V. **The Need for FDA to Issue Federal Licensure Standards**. HDA believes that the DSCSA's mandate for uniform federal licensure standards for wholesale distributors and third-party logistics providers is being undermined by state licensure requirements that are inconsistent with the DSCSA. HDA urges FDA to issue federal licensure standards as quickly as possible.

VI. **The Need for FDA Guidance on GS1 Standards, Product Identifiers, NDC Conversion, and Barcode Formatting**. Trading partners are adopting and using GS1 standards for DSCSA implementation, including use of Electronic Product Code Information Services (EPCIS) to exchange transaction data, Global Location Numbers (GLNs) to identify locations, and Global Trade Identification Numbers (GTIN) as part of product identifiers. Movement to

2023 standardization would be aided and trading partner uncertainty reduced if FDA expressly supported use of GS1 standards for EPCIS, GLNs, and GTINs. FDA's support for the HDA guidance on barcodes would help with appropriate placement and readability of barcodes on products and homogenous cases.

VII. **Mismatches Between Product and DSCSA-related Data Should Not Automatically Render a Product to be Suspect or Illegitimate**. HDA asks that FDA (1) recognize important distinctions between true suspect or illegitimate product situations and commercially routine exceptions between established trading partners, and (2) a mismatch between product and DSCSA-related data does not automatically render a product to be suspect or illegitimate.

VIII. **The HDA Saleable Returns Pilot and Manufacturer Serialization Readiness Survey**. HDA briefly summarizes a pilot to examine different methods for verifying product identifiers on saleable returns in an effort to better understand the operational impact of the 2019 DSCSA requirements, and how manufacturers and wholesale distributors can meet these requirements. Also provided is a link to the final report of a "Manufacturer Serialization Readiness Survey" HDA recently conducted. We urge FDA to use the information learned from these activities to inform any further support the Agency may provide.

IX. **DSCSA Focus Upon Building Toward a 2023 System**. HDA agrees with other stakeholders that, ideally, systems used to support industry compliance with 2019 verification requirements will continue to have utility in the 2023 interoperable, electronic system. HDA recommends that FDA continue its collaboration with the supply chain to assess 2019 and 2023 systems and announce as early as possible if the agency sees approaches that it views as out of alignment with the agency's own interpretations of DSCSA requirements.

X. **The Need for Guidances on Grandfathering and Waivers, Exceptions, and Exemptions**. HDA hopes that FDA will release these guidances soon.

We also attach an Addendum discussing the challenges presented by the conflict between U.S. and India traceability requirements.

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HDA thanks you for this opportunity to provide initial remarks and suggestions on progress toward implementing the product identification and other requirements of the DSCSA. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca

Anita T. Ducca
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Attachments