

# Client Alert

Special Matters & Government Investigations Practice Group

July 1, 2015

## **FDA Announced a Four-Month Enforcement Delay on Certain Drug Supply Chain Security Act Product Tracing Requirements for Dispensers**

FDA Does Not Intend to Enforce Product Tracing Requirements Related to Dispensers' Receipt and Maintenance of Product Tracing Information Until November 1, 2015. It Did Not Delay Dispenser Requirements With Respect to Product Verification and Authorized Trading Partners.

### *Summary*

On June 30, 2015, the Food and Drug Administration (FDA) issued guidance for the pharmaceutical industry regarding the implementation of the Drug Supply Chain Security Act's (DSCSA) product tracing requirements for dispensers. In this guidance, FDA announced that it "does not intend to take action against dispensers" that fail to capture and then maintain product tracing information from their trading partners prior to November 1, 2015. The obligation for dispensers to capture and maintain this information takes effect on July 1, 2015.<sup>i</sup>

FDA has not delayed enforcement of any of the other dispenser requirements that take effect on July 1. Specifically, entities that qualify as "dispensers" under the DSCSA are still expected to verify suspect and illegitimate products and to transact only with authorized trading partners beginning on this date.<sup>ii</sup>

The guidance also acknowledged the end of a similar four-month enforcement delay that FDA had granted on December 31, 2014, to entities that qualify as "manufacturers," "wholesale distributors," and "repackagers."<sup>iii</sup> That delay had postponed FDA enforcement of those entities' obligations with respect to product tracing information.<sup>iv</sup>

### *Background*

The DSCSA was signed into law on November 27, 2013. Its requirements are intended to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed throughout the United States by November 27, 2023. The system will enhance the ability to verify legitimate drug products, detect illegitimate products, and recall potentially dangerous products.<sup>v</sup>

The DSCSA affects manufacturers, wholesale distributors, repackagers and certain dispensers of "products"—generally, prescription drugs in a finished dosage form for administration to a patient.<sup>vi</sup>

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## *Implications*

While FDA has delayed its enforcement of *dispensers' obligations* to receive and maintain the DSCSA's three required types of product tracing information (Transaction History, Transaction Information, and a Transaction Statement),<sup>vii</sup> it has not provided any additional extension of time for other entities in the supply chain to transmit the three types of product tracing information both among themselves and to dispensers.

Based on the experience of the manufacturers, wholesale distributors, and repackagers, dispensers should not expect to receive any additional extensions from FDA regarding the enforcement of these product tracing requirements. Dispensers should act diligently to put in place systems to receive product tracing information prior to or at the time they take ownership of a product and to implement policies and procedures governing the acceptance and maintenance of this information.

In addition, dispensers must immediately verify suspect and illegitimate products and limit their transactions to authorized trading partners. Satisfactory policies and procedures should already be in place to: (1) confirm the licenses or registrations of their trading partners,<sup>viii</sup> and, (2) identify; quarantine, and investigate suspect product.<sup>ix</sup>

Finally, any dispenser that engages in transactions as a wholesale distributor under the DSCSA must transmit product tracing information effective July 1, 2015. Dispenser/distributors that fail to do so leave themselves open to enforcement action from FDA for violations of the DSCSA.

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<sup>i</sup> U.S. Dep't of Health & Human Servs., Food & Drug Admin., *DSCSA Implementation: Product Tracing Requirements for Dispensers — Compliance Policy, Guidance for Industry* (July 2015), p. 1, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM453225.pdf> (last visited July 1, 2015).

<sup>ii</sup> *Id.* at p. 3.

<sup>iii</sup> *Id.*

<sup>iv</sup> U.S. Dep't of Health & Human Servs., Food & Drug Admin., *DSCSA Implementation: Product Tracing Requirements — Compliance Policy, Guidance for Industry*, p. 1 (Dec. 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf> (last visited July 1, 2015).

<sup>v</sup> *Id.* at p. 2.

<sup>vi</sup> The covered entities and products are each defined in the Federal Food, Drug & Cosmetic Act (FDCA). *See* 21 U.S.C. § 360eee.

<sup>vii</sup> The elements of each of these three types of information are set forth in the FDCA. *See id.*

<sup>viii</sup> *Id.* at § 360eee1–(d)(3).

<sup>ix</sup> *Id.* at § 360eee1–(d)(4)(A)–(B).