

Countdown to the End of DSCSA Stabilization:

HDA Urges FDA To Take a Forward-Leaning Approach to Final Months of Implementation



With less than a year left until the end of the Food and Drug Administration's (FDA) stabilization period for the Drug Supply Chain Security Act (DSCSA), the Healthcare Distribution Alliance (HDA) and its members are calling on FDA to take an assertive and forward-leaning approach to the final phase of the law's implementation.



HDA previously recommended FDA adopt and recommend phased milestones for industry sectors throughout the stabilization period in 2024 to allow for adequate time to put in place the complex processes necessary for compliance and tracing at the package-level and ensure a smooth transition to full implementation. Since issuing the Stabilization Policy, the FDA has yet to adopt such an approach. Without additional direction from the FDA, HDA's members have reported continued compliance issues with trading partners.

HDA members have expressed concern that without a clear picture of the state of the supply chain right now, there could be significant supply chain disruptions that could contribute to drug shortages and patient access to needed medications at the end of the Stabilization Policy. By providing additional guidance to trading partners, the FDA will be able to help ensure medicines can continue to make their way to patients safely and securely, while still achieving the package-level tracing and the enhanced supply chain security Congress envisioned.

To ensure the pharmaceutical supply chain is ready on November 27, 2024, [HDA has asked FDA¹ to:](#)

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USE THE INFORMATION COLLECTED FROM THE RFI TO PROMPTLY COMPOSE A COMPREHENSIVE PICTURE OF SUPPLY CHAIN READINESS.

- FDA sits in the best position to leverage information collected from the RFI to depict a view of supply chain progress and identify gaps in readiness.
- The agency should promptly inform stakeholders of what the FDA believes is the state of DSCSA compliance by May 1, 2024, which would demonstrate the FDA's commitment to timeliness and efficiency.

2

ACKNOWLEDGE THE REALITY OF READINESS IN THE SUPPLY CHAIN AND ADVISE THE INDUSTRY OF THE FDA'S INTENTION TO USE ENFORCEMENT APPROACHES FOLLOWING THE END OF THE STABILIZATION PERIOD.

- It is important for the FDA to issue details about its intended enforcement approaches post-November 27, 2024, informed by industry-submitted data to foster trust and collaboration and motivate those who continue to delay implementation into compliance.
- The FDA should consider the nature of the violation and a trading partner's documented good faith efforts to ensure equitable enforcement. This approach would incentivize positive behavior through recognition and support.
- The FDA needs to collaborate more openly with state regulators about trading partners' obligations under the law. Without collaboration, the FDA risks replicating the pre-DSCSA patchwork of state regulations and interpretations.

3

COMMIT TO INTENSIVE COMMUNICATION STRATEGIES DURING THE REMAINDER OF THE STABILIZATION PERIOD, INCLUDING ISSUING TARGETED "DEAR TRADING PARTNER" LETTERS.

- For the remainder of the stabilization period, HDA urges FDA to bolster its members' continued compliance efforts by communicating with trading partners in a stepwise approach to help them understand their obligations under the law.
- "Dear Trading Partner" letters should address each sector, outlining requirements and potential enforcement approaches. Letters to manufacturers and repackagers should be sent no later than May 1, 2024, with letters to the wholesale distributor and dispenser sectors following at a staggered pace.

¹ HDA submitted comments to the FDA's request for information on "Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act" (RFI). The RFI asks how trading partners are using the stabilization period to troubleshoot and mature secure, electronic, interoperable systems and processes for enhanced drug distribution security, as required under the DSCSA. The RFI also seeks information on the successes and strategies that trading partners have implemented since FDA announced its Stabilization Policy.

For more information about the distribution industry's approach to pharmaceutical traceability and DSCSA implementation, visit: www.hda.org/pharmaceutical-traceability.