RESOURCES



Get Answers to Frequently Asked Questions About the FDA's 12-Month DSCSA Stabilization Period

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This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

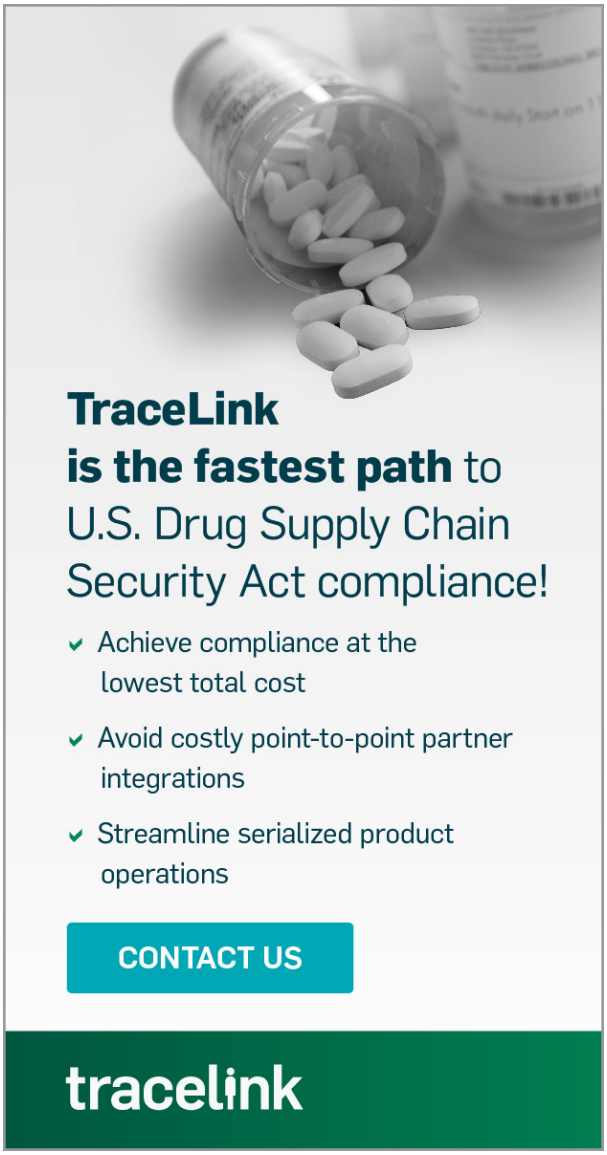
In recent guidance issued to the pharmaceutical industry, the U.S. Food and Drug Administration (FDA) announced a 12-month enforcement discretion and system stabilization period for the final phase of the U.S. Drug Supply Chain Security Act (DSCSA), but the law will still take effect on November 27, 2023. In this article, the TraceLink team answers frequently asked customer questions about the stabilization period and what it means for U.S manufacturers, wholesale distributors, and pharmacies.

What does the FDA enforcement guidance mean?

The **FDA enforcement guidance** was published to provide the industry with additional time to implement, troubleshoot, and mature its DSCSA solutions.

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During the additional 12-month period, referred to as a stabilization period, the FDA indicated that it will use discretion when enforcing the law between November 27, 2023 and November 26, 2024.



Why did the FDA take this action?

Over the past several months, the FDA has listened to members of the industry to assess industry readiness. During this time, the FDA determined that the industry would not be ready to meet all requirements by November 27, 2023. As a result, those trade partners would not have been able to legally ship or receive medicines beginning on November 27th. The FDA announced the stabilization period to enable the pharmaceutical industry to avoid supply disruptions and negative

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impacts to patient health.

Does this mean that the law has been delayed?

No. DSCSA is a federal law and the FDA does not have the authority to change the deadlines defined in the law. Changing the deadlines would require a modification of the law to be proposed and approved by Congress. This process usually takes years and there is no indication that this will happen.

Does this mean companies should stop their projects or delay a solution purchase?

No. The FDA guidance document on delaying compliance projects is very clear:

"This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements."

Enforcement discretion has been used multiple times with DSCSA. How do we know the FDA will not issue another enforcement discretion period extending beyond November 27, 2024?

The November 27, 2023 deadline is the last of a series of DSCSA requirements that went into effect over the past ten years. The FDA has stated that it expects the industry to comply with the law and that the law will not be abolished. The agency, however, has recognized that the industry has consistently underestimated the time to deploy and stabilize their systems. In the past, the FDA has provided one period of DSCSA enforcement discretion.

How should companies interpret the FDA’s actions?

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With this announcement, the FDA has removed any ambiguity related to the implementation of DSCSA. The guidance document clearly states the FDA's intention to enforce these requirements starting November 27, 2024. Companies should interpret this as the date by which they should be fully compliant. Compliance projects should begin well before this date. The FDA will look for companies that stop or significantly delay projects and will enforce the law when companies are not working within the spirit of the stabilization period.

How can TraceLink help?

Customers that are not already working with TraceLink on DSCSA compliance should immediately contact their account executive for advice on how to initiate an engagement to become compliant. For many customers, this can be done in a few days or weeks. If you are not currently a customer, TraceLink's turnkey DSCSA Compliance solutions are the fastest and lowest-cost path to compliance. **Contact TraceLink today to learn more**.

Watch this **on demand webinar** for more information on the DSCSA stabilization period.

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Thank you for contacting us; we'll be in touch shortly.

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