FDA Reiterates: No Extensions to the DSCSA Stabilization Period



With the end of the DSCSA stabilization period drawing near, the FDA reiterated at the 2024 FDLI Annual Conference that there will be no extensions to the DSCSA stabilization period.

What does this mean for the pharmaceutical and healthcare industry? This article looks at the FDA's recent remarks and how TraceLink can help you ensure you're ready in time for the end of the DSCSA stabilization period on Nov. 27.

No more "kicking the can down the road"

At the 2024 Food and Drug Law Institute Annual Conference, the FDA's Director of the Center for Drug Evaluation and Research (CDER) Patrizia Cavazzoni fielded questions on the U.S. Drug Supply Chain Security Act (DSCSA) and compliance timelines. She stressed that the FDA remains firm in its stance: the organization does not intend to extend the DSCSA stabilization period.

"I really want to emphasize that this is not really a matter of kicking the can down the road," Cavazzoni said, as reported by Regulatory Focus. She further reaffirmed that pharmaceutical and healthcare companies should be using the extra 12 months afforded by the DSCSA stabilization period to finish troubleshooting their

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systems and processes for DSCSA compliance.

The FDA is in the process of finalizing its own preparations as well. Cavazzoni told the crowd that CDER's NextGen Portal, a tool for communicating with the FDA for drug recalls and suspect product investigations, is currently live and will be ready to accept DSCSA-related compliance documents in November.

Subsequently, the FDA announced on June 13 that **it would grant small dispensers exemptions** from certain requirements until November 27, 2026. These exemptions only apply to certain requirements of section 582 of the FD&C Act, and only to dispensers with 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians.

DSCSA: A lot to do and only a little time to do it

The implications of the FDA's recent statements are clear: all companies in the pharmaceutical supply chain barring small dispensers must have DSCSA-compliant processes and systems operational by November. Those that aren't ready may face regulatory fines in addition to other complications such as product shortages, operational disruption, and trade partner penalties.

While many companies in the pharmaceutical and healthcare industry have at least begun their DSCSA compliance efforts, the reality is that the scope of technical and operational change required by DSCSA is extensive. Even those that have addressed the technical requirements of DSCSA and are able to electronically exchange EPCIS with their trade partners will still need a plan for things like:

- **DSCSA scalability testing:** What scalability testing have you completed with your trade partners? Are their systems capable of receiving the standard EPCIS messages describing 100's, 1000's or 100,000's of your products? If your customers are not able to process transactions at scale, acceptance of your product may be at risk.
- **DSCSA exceptions:** There will be an influx of compliance-related exceptions as the industry gets accustomed to sending EPCIS in a live environment. Do you have the capabilities to resolve these exceptions with your trade partners

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quickly so they don't disrupt your sending and receiving processes?

- **DSCSA standard operating procedures (SOPs):** What are your processes for inspecting product identifiers? Do you have systems in place for storing product tracing data in compliance with the DSCSA? What happens when trade partners send a suspect or illegitimate product notification?

DSCSA touches several areas of operations and there is not a lot of time to prepare—Nov. 27 is less than 173 days away. Will you be ready in time?

TraceLink offers the fastest path to DSCSA compliance

The good news is that no matter where you are in your DSCSA compliance project, you can still achieve compliance before the end of the DSCSA stabilization period. However, you do need to act quickly. Companies should expect a surge in activity as the deadline nears, making it more difficult for your partners to respond to everyone in a timely manner.

TraceLink offers the fastest, lowest-risk and lowest cost of ownership to achieving DSCSA compliance by Nov. 27. Our network-based approach to integration enables companies to connect with hundreds or even thousands of trade partners through a single integration to the TraceLink network, after which you can begin exchanging serialized T2 product data in compliance with the DSCSA. To date, TraceLink has implemented more than 5,500 DSCSA transaction integrations, with more than 2 million DSCSA EPCIS transactions exchanged in the last two months alone.

In addition to enabling the electronic exchange of EPCIS, TraceLink's network solution also provides capabilities for accelerating and simplifying processes surrounding DSCSA. This includes working with end-to-end trade partners to resolve compliance exceptions through a single shared application and streamlining product verification with a comprehensive interoperable lookup directory.

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All of these processes and capabilities are supported by TraceLink's resilient and adaptable network architecture. The TraceLink network is continually maintained by our internal team on your behalf, so you never have to worry about managing integrations or updating your software to accommodate standards changes. TraceLink also has well over 200 people on our support team, ready to assist with and troubleshoot any obstacles encountered on your path to DSCSA compliance.

TraceLink is happy to review your DSCSA project ahead of Nov. 27. If you're using a competitor's solution, it's not too late to switch—just fill out this form and we'll get in touch promptly to assess your requirements. If you're a TraceLink customer with any questions, contact your account executive for a deeper discussion on your implementation.

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Contact TraceLink to review your DSCSA strategy!
Fill out the form to schedule a review now.

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

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