What's Next After FDA's DSCSA Extension?

APPENDIX B

DSCSA Implementation: FDA & Industry Collaboration (2014-24)

I would be remiss if I did not recognize and applaud all the well-meaning and dedicated people in FDA and industry who have worked so hard over the last 11 years to bring DSCSA interoperability into the implementation "red zone" and so close to the goal line, even as the goal posts had to be moved a few times along the way.

There has been great collaboration, discussion, and debate across trading partners along this journey.

This table highlights the steady stream of communication and listening that has helped to advance DSCSA implementation.

FDA & INDUSTRY COLLABORATION THROUGHOUT DSCSA 11-YEAR ROLL OUT	
Oct. 9, 2024	FDA grants exemption to connected trading partners in staggered duration for each ATP
September 2024	FDA joint stakeholder listening sessions with distributors and dispensers; reported by PDG
June 27 - Aug. 8, 2024, Aug. 26-28, 2024	HDA traceability webinar series & HDA 2024 traceability seminar, Washington, DC
June 29, 2024, Aug. 19, 2024	NACDS phased, stepwise approach & HDA phased milestones with narrow guardrails letters to FDA RFI focket
June 17-18, 2024, Presented July 25, 2024, Published	PDG DSCSA stabilization survey narrative results
June 17-18, 2024	PDG-FDA joint public meeting: "DSCSA Stabilization Period Midway Checkpoint"
June 12, 2024	FDA reopening of comment period docket No. FDA-2023-N-4806 RFI & comments
June 12, 2024 Revised edits July 12, 2024	FDA grants exemption to small dispensers ** (≤ 25 FTEs) to 2026, fully 3 years past 2023 mandate
Feb. 27-28, 2024	Partnership for DSCSA Governance (PDG) workshop suspect & illegitimate product investigations

By Carl Accettura, Global Pharma Advisory

Nov. 20, 2023	Docket No. FDA-2023-N-4806 RFI & comments re: implementing DSCSA interoperable systems and processes for EDDS requirements
Aug. 29-31, 2023	HDA 2023 Traceability Seminar, Washington, DC
Aug. 28, 2023	FDA DSCSA compliance policies establish 1 year of enforcement discretion during stabilization period to implement EDDS system; law takes effect nonetheless.
June 2, 2023	HDA Letter to FDA pre-stabilization proposal Phased approach to interoperable electronic exchange of product identifiers in transaction info
Feb. 6-7, 2023	Partnership for DSCSA Governance (PDG) workshop suspect & illegitimate product investigations
Feb. 6-7, 2023	Exceptions handling workshop PDG-HDA-GS1 jointly hosted, with FDA participation
Oct. 12-14, 2022	HDA 2022 traceability seminar, Washington, DC
June 15-16, 2022	PDG pilot tabletop and workshop
2021-2023	PDG foundational blueprint framework for 2023 Interoperability
Pandemic times October 2020	FDA enforcement discretion adds a 3-year delay from the delay set forth in the 2019 compliance policy
Sept. 16, 2020	PDG public private partnership with FDA announced
Pre-Pandemic Sept. 23, 2019	FDA enforcement discretion for wholesale distributors 1-year, to Nov. 27, 2020, to verify product identifiers

November - December, 2019	PDG industry consortium. 60+ pharma supply chain stakeholders' goal: establish and advance industry consensus for interoperable DSCSA systems
July 3, 2019	Pharma distribution supply chain pilot projects; FDA reopens RFI comment period
July 2017 - February 2018	FDA held 3 public meetings with stakeholders and opened Docket No. FDA-2017-N-3857: 1. Refine Enhanced Drug Distribution Security (EDDS) 2. Building capacity for a unit-level system 3. Verification of the DSCSA Product Identifier 4. Identification and prioritization of “Guardrails” 5. Electronic interoperability, data exchange standards, data architecture, aggregation & inference
June - December 2017	FDA enforcement discretion for manufacturers *** 1-year, to Nov. 27, 2018, to imprint a product identifier to each package and homogenous case of product; grandfathering guidance for product in supply chain
Prior to mandated unit-level serialization (2017), saleable returns verification (2019) and EDDS implementation (2023), during implementation of TI/TH/TS (T3) data exchange, FDA allowed enforcement discretion for ATPs.	
2014 - 2015	FDA enforcement discretion for TI/TH/TS exchange delayed by staggering dates for all ATPs ***