

FDA — DSCSA: Track and Trace

Phase 1: Lot Level Traceability

- Authorized trading partner verification (1/15)
- Suspect/illegitimate product identification and notification (3/16)
- Transaction data (1/15 & 3/16)

Phase 2: Product Identifier (PI)

- Manufacturers add PI to unit/case, and build a database (11/17)
- Re-packagers add PI to unit/case (11/27/18)
- Wholesaler transactions with identified products (11/19)
- Dispenser transactions with identified products (11/20)

Phase 3: Unit Level Traceability

- Unit-level traceability for all supply chain stakeholders (11/23)
- Track and exchange unit-level serialized data (11/23)



APhA

PHARMACISTS
PROVIDE CARE

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Additional Provisions for FDA:

- Small pharmacy technology assessment on package-level tracing (2020)
- Establish and evaluate pilot projects on enhancing supply chain safety/security (initial steps underway)
- Regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level (2021)
- Final guidance on interoperable data exchange standards for secure package level product tracing (2022)

