

DSCSA TIMELINE FOR IMPLEMENTING THE DRUG SUPPLY CHAIN SECURITY ACT

NOVEMBER 27, 2013

Congress enacts the Drug SUpply Chain Security Act (DSCSA)

MAY 26, 2014

The FDA draft guidance on suspect product and terminating notifications

NOVEMBER 27, 2014

JULY 1, 2015

Standards published for Transaction Information (TI), Transaction History (TH), and Transaction Statement (TS) [Collectively know as T3]

Third Party Ligistics (3PL) licensure reporting begins

Dispensers begin providing

T3 information to trading partners

JANUARY 1, 2015

Trading partners must be authorized. Manufacturers must print lot numbers of packaging for all prescription drugs

Manufacturers send and Wholesale Distributors receive T3 and begin direct purchase statement

Wholesale distribution licensure reporting begins

FDA establishes publicly available database of wholesale distributors

MARCH 1, 2016

T3 enforcement discretion ends

NOVEMBER 27, 2017

Manufacturers serialize product

Manufacturers verify Standardized Numerical Identifiers (SNI)

T3 transmitted electronically

Federal distributor licensure regulations effective

NOVEMBER 27, 2018

Repackagers serialize product

Repackagers associate & verify SNI

OCTOBER 23, 2019

FDA delays enforcement of salable returns requirements by 1yr for Wholesale Distributors

NOVEMBER 27, 2019

Wholesale Distributors receive and distribute serialized products

Wholesale Distributors verify SNI, including returns

OCTOBER 23, 2020

FDA delays enforcement of salabe returns requirements by 3 years for Wholesaler Distributors and Dispensers

NOVEMBER 27, 2020

Dispensers receive and ship serialized data

Dispensers verify SNI

NOVEMBER 27, 2023

Full interoperable electronic unit-level traceability for all stakeholders

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NOVEMBER 27, 2015

National standards for Wholesale Distributor licensure issued

National standards issued for 3PLs

Waiver guidance issued for exchange of T3

Standards issued for exceptions to Product Identifier requirements

Standards issued for grandfathering product database of wholesale distributors

2020

2019

2023

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