Drugs

Drug Supply Chain Security Act (DSCSA) Implementation Plan

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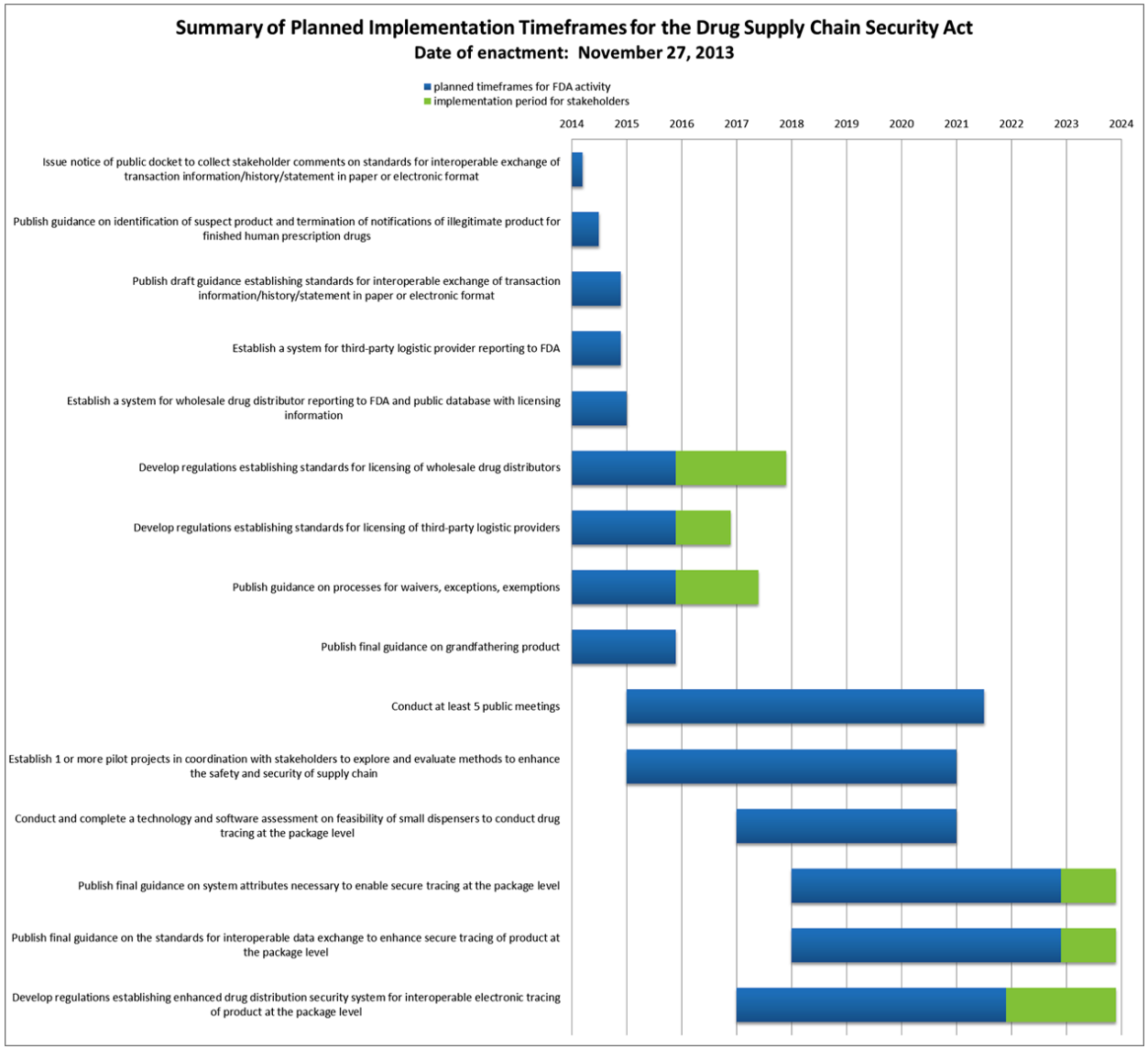
The following graphic represents a summary of planned implementation timeframes for the Drug Supply Chain Security Act [2]over a 10-year period. Timeframes are estimates and are based on the requirements set forth in the law. This implementation plan will be updated as appropriate.



The following table highlights certain deliverables described in the law. Estimated target dates are based on applicable statutory deadlines and may be listed as "TBD" (to be determined) when dependent on completion of other deliverables or activities. As FDA works with stakeholders to implement the provisions of the law, additional deliverables may be identified. FDA's Center for Drug Evaluation and Research is the lead for the Drug Supply Chain Security Act Implementation and other agency components are actively engaged.

Section of DSCSA	Deliverable Type	Deliverable Description	Estimated Target Date

202	FR Notice[3]	Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information/history/statement in paper or electronic format	2/20/2014
202	Guidance	Publish draft guidance establishing standards for interoperable exchange of transaction information/history/statement in paper or electronic format	11/27/2014
202	Guidance	Publish guidance on processes for waivers, exceptions, exemptions	11/27/2015
202	Guidance	Publish final guidance on grandfathering product	11/27/2015
203	Assessment	Conduct and complete a technology and software assessment on feasibility of small dispensers to conduct drug tracing at the package level	TBD
203	Guidance[4]	Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs	5/27/2014
203	Public Meeting	Conduct at least 5 public meetings	TBD
203	Pilot Project	Establish 1 or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain	TBD
203	Guidance	Publish final guidance on system attributes necessary to enable secure tracing at the package level	11/27/2022
203	Guidance	Publish final guidance on standards for interoperable data exchange to enhance secure tracing of product at the package level	11/27/2022
203	Regulation	Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level	11/27/2021
204	Database	Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information	1/1/2015
204	Regulation	Develop regulations establishing standards for licensing of wholesale drug distributors	11/27/2015
205	Database	Establish a system for third-party logistic provider reporting to FDA	11/27/2014
205	Regulation	Develop regulations establishing standards for licensing of third-party logistic providers	11/27/2015

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