Drug Product Tracing: The Effect of Section 585 of the FD&C Act

Questions and Answers Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

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Contains Nonbinding Recommendations

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I. INTRODUCTION

The Food and Drug Administration (FDA) is issuing these questions and answers to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[2] (21 U.S.C. 360eee-4), added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013, on drug product tracing. Title II, which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. Section 585 requires there be a uniform national policy, preempting States[3] from establishing or continuing in effect certain standards and requirements. FDA is issuing this guidance to: (1) help industry and States understand the law as it is currently in effect; and (2) clarify the effect of section 585(a) on any regulation of drug product tracing by States.[4]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required."

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] For brevity, in this guidance, references to section 585 of the FD&C Act are cited as *section 585*.

[3] Section 585 uses the phrase "State and political subdivision of a State." For purposes of this document, the word *States* will mean States and political subdivisions of States.

[4] This guidance does not cover the effect of section 585(b) of the FD&C Act, given that section 585(b) is further explained in the proposed rule for part 205 that establishes the standards for licensing wholesale distributors and third party logistics providers.

II. BACKGROUND

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA adds sections 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section 581), requirements for supply chain participants (section 582), standards for and licensing of wholesale drug distributors (section 583) and third-party logistics providers (section 584), and a Uniform National Policy (section 585).

Section 585(a), as added by section 205 of the DQSA, states:

> (a) Product Tracing and Other Requirements.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—
>
> (1) any waiver, exception, or exemption pursuant to section 581 or 582; or
>
> (2) any restrictions specified in section 582.

This guidance focuses only on the effect of section 585(a) on product tracing and other requirements established by the States.

III. PRODUCT TRACING QUESTIONS AND ANSWERS

1. How does section 585(a) affect State product tracing requirements?

Beginning on November 27, 2013, the date of enactment of the DSCSA, States were preempted from establishing or continuing in effect any requirements for tracing prescription drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act (21 U.S.C. 353(e) (as amended by the DSCSA)) or Subchapter H (added by the DSCSA) or regulations issued thereunder.

Section 585 enumerates the types of requirements that States are preempted from establishing or continuing in effect in any manner that is inconsistent with, more stringent than, or in addition to Federal law, including: statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, verification, investigation, disposition, notification, or recordkeeping relating to the

distribution systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

In addition, no State may establish, continue in effect, or apply any requirement that is inconsistent with any waiver, exception, or exemption granted by FDA pursuant to sections 581 or 582 of the FD&C Act or any restrictions specified in section 582.

2. What product tracing requirements applied before January 1, 2015?

Prior to January 1, 2015, the Federal pedigree requirements of section 503(e)(1) of the FD&C Act, remained in effect.

3. What product tracing requirements apply on or after January 1, 2015?

Beginning January 1, 2015, the Federal product tracing requirements of section 582 of the FD&C Act established under the DSCSA, went into effect. After that date, States could no longer regulate product tracing in any way that is inconsistent with, more stringent than, or in addition to those requirements.

4. Which State requirements are preempted?

Any requirements for tracing drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act, as amended by the DSCSA, or under subchapter H (or regulations issued thereunder) are preempted.