Biotechnology Industry Organization

January 27, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-1981: The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on "The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information."

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO would like to thank the FDA for the flexibility provided in the Draft Guidance for Stakeholders to exchange transaction information, transaction history, and transaction statement (TI/TH/TS) required by the Drug Supply Chain Security Act (DSCSA) beginning January 1, 2015. BIO members have been working diligently with their trading partners to implement the DSCSA and we are pleased that the Draft Guidance allows stakeholders to move forward with the processes and methods already established between trading partners, as long as these methods "allow information to be exchanged in a manner that complies with the requirements" of the law.

BIO also appreciates FDA's intention to issue additional guidance regarding standardization of data and documentation practices. We look forward to additional insights on the Agency's current thinking and welcome the opportunity to provide comments. We hope that FDA continues to embrace a similar flexible and practical approach.

We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

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Managing Director, Science and Regulatory Affairs
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