Biotechnology Industry Organization

April 21st, 2014

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

Re: Docket No. FDA-2014-N-0200: Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the Request for Information (RFI) on "Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format."

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 is an active member in the Pharmaceutical Distribution Security Alliance (PDSA) and fully supports their response to this Request for Information. We would like to echo that while manufacturers are committed to transitioning to an all-electronic system for passing Transaction History, Transaction Statement, and Transaction Information (TH/TS/TI), we recognize the need for flexibility for some of our trading partners and across the supply chain in the near future. Any electronic system - even those that are based on a common standard or may be interoperable - will require modifications and testing before trading partners can successfully exchange TH/TS/TI electronically. As such, we foresee the need for a temporary hybrid system of passing information, and ask FDA to accommodate paper solutions in the near term.

We also ask that FDA work with stakeholders to evaluate possible long term solutions and standards as the supply chain moves to a standardized, interoperable system.

Finally, as FDA's planned Draft Guidance on establishing standards for interoperable exchange will be an integral guide for companies' decisions regarding electronic

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systems and ultimate compliance with the Drug Supply Chain Security Act (DSCSA), we respectfully ask FDA to release this document in advance of the November 2014 statutory deadline.

Thank you and we would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Victoria Dohnal
Manager, Science and Regulatory Affairs,
Biotechnology Industry Organization (BIO)