BIOTECHNOLOGY INDUSTRY ORGANIZATION

1201 Maryland Avenue SW, Suite 900, Washington, DC 20024
202-962-9200, www.bio.org

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2008N–0121: Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments and provide requested information on *Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication.* BIO welcomes FDA's request for information as a promising step towards establishing a uniform national standard for product serialization and electronic track-and-trace for prescription drugs. BIO represents more than 1,200 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 technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

The biotechnology industry brings a unique perspective toward efforts to improve the pharmaceutical supply chain. Biologics are complex medicines that are manufactured using living organisms. These drugs are different and far more complicated than most small molecule chemical drugs. Due to their complexity, biologics require special handling and care and are often shipped through "specialty" distribution channels or direct drop shipments to the provider with additional precautions such as preserving the cold chain. These additional precautions ensure the safety and efficacy of the product, but also pose challenges when establishing a uniform national distribution practices. For that reason, BIO supports interoperable, standards-based approaches to track-and-trace

that are technology neutral, thereby allowing manufacturers to deploy product-appropriate solutions. Indeed, manufacturers are the most knowledgeable about their products, packaging, and distribution and are best suited to determine the appropriate anti-counterfeiting technology or data carrier for that particular product. Anti-counterfeiting technologies continuously evolve and change in response to the constantly changing threat of counterfeiting and the technological sophistication of counterfeiters, and consistent with FDA regulations, manufacturers should continue to decide which anti-counterfeiting measures should be applied to the product to ensure patient safety.

GUIDANCE IS NEEDED ON THE TESTING OF RFID ON BIOLOGICS:

Two of the most commonly discussed serialized data carriers are 2-D barcode and Radio Frequency Identification Tags (RFID). Both technologies can carry adequate data to validate a product's transaction history and enhance inventory management. However, at this time it is uncertain how the radio emissions emitted by RFID readers impact the molecular stability of therapeutic proteins and biologics. Due to this uncertainty, FDA's RFID Compliance Policy Guide has stated since 2004 that that the agency would not exercise enforcement discretion for RFID feasibility studies conducted on biologics, thereby discouraging an RFID pilot program on biologic products. The Compliance Guide further states that "At this time the agency does not have the necessary scientific data to extend its exercise of enforcement discretion to RFID studies for all products." Since the release of the compliance guide, there has only been limited research conducted on impact of radiofrequency emissions on the safety and efficacy profiles of biologics. In addition, there are concerns that the metal and liquids in product vials may interfere with RFID reads and decrease the efficiency of the system.

Before RFID could be considered as a candidate for track-and-trace technology for biologics, we urge FDA to commission additional scientific collaborative studies with industry and academic institutes to evaluate the potential impact of radiofrequency emissions on biologics. We also request that FDA provide additional guidance to industry on RFID testing protocols for biologics. BIO and its member companies would be pleased to work with the agency to help develop these protocols.

2-D BARCODES AND SCALABLE TECHNOLOGIES:

Consistent with the FDAAA § 913 requirement to address promising technologies including "other track-and-trace or authentication technologies," FDA should further evaluate the relative merits of 2-D barcodes for biologics distribution. Industry has made significant investments in evaluating various technologies and developing standards, including GS1's coding standards for 2-D bar codes. In the interests of global harmonization (Europe has widely adopted 2-D bar codes) and leveraging current initiatives by industry, FDA's efforts should not exclude 2-D bar codes from consideration. Furthermore, any standards initially developed should be basic but scalable so that smaller companies can more readily comply, while larger companies can adopt additional functional elements needed to better serve their business.

RISK-BASED IMPLEMENTATION UNDER REASONABLE TIMEFRAMES:

Despite our desire not to see 2-D bar coding excluded by FDA, several of our members have experienced challenges with respect to 2-D bar code serialization on high speed pharmaceutical packaging lines. For this reason, a reasonable timeline for wide scale adoption of track and trace technologies is essential. Additionally, in light of the difficulties existing for 2-D bar coding on high speed pharmaceutical packaging lines, a risk-based implementation approach is desirable as it would permit industry to develop the technology and experience needed to ensure reliability while at the same time focusing efforts on those products most at risk.

COMPARISONS OF AVAILABLE TECHNOLOGIES:

BIO notes the following with respect to RFID, nanotechnology and other optical bar code-like technologies:

Technology	Strengths	Limitations
2-D Barcode and other optical bar code-like technologies	• Can carry all data necessary to enable a pedigree or allow track-and-trace • Does not issue radio emissions and can be used with biologics • Established standards and reliability • Extensive supply chain experience with bar-coding systems • Cost-effective ongoing costs and maintenance • Easier for small businesses to adopt and scale-up • Consistent with current FDA bar-code regulations	• Line of sight necessary for read • Not typically in public domain so difficult to standardize • Requires investment in readers and possible infrastructure upgrades
RFID	• Does not require line-of-sight data capture • Can contain more data than bar codes • Can incorporate encrypted information for authentication purposes • UHF standards exist (EPC), but many RFID standards currently remain under development and untested • Gaining acceptance in other fields such as consumer products and transportation	• Technology not robust for certain applications (metal and liquids) • Effects not known for biologics • Limited data about wide-scale implementation with pharmaceuticals • Lack of standards for item level (UHF versus HF) • Currently need bar code backup • Requires investment in readers and possible infrastructure upgrades • Privacy and security concerns
Nanotechnology		• No clear application of technology for purposes of identification, validation, track and trace, or authentication

Other preferences identified by our members include a recommendation that identifiers be both machine readable and human readable to ensure that parties throughout the supply chain have a backup system.

CONCLUSION:

BIO appreciates this opportunity to comment on *Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information.* We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization