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January 9, 2012

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

Re: Docket No. FDA–2011-N-0719: Bar Code Technologies for Drugs and Biological Products; Retrospective Review under Executive Order 13563; Request for Comments

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to submit comments on the "Retrospective Review under Executive Order 13563: Bar Code Technologies for Drugs and Biological Products."

BIO represents more than 1,100 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.

I. *Retrospective Review Under Executive Order 13563 and the Bar Code Final Rule*

BIO thanks the FDA for considering our previous comments and recommendations on the "Periodic Review of Existing Regulations; Retrospective Review under Executive Order 13563."[1] We applaud efforts to revise existing regulations to increase flexibility and global

[1] Biotechnology Industry Organization, *Periodic Review of Existing Regulations; Retrospective Review under Executive Order 13563* (Docket No. FDA-2011-N-0259), June 27, 2011, available at http://www.bio.org/sites/default/files/20110627_regulatory_reform.pdf.

harmonization in the regulatory environment. Such changes have the potential to result in efficiencies across industry and improvements in public health. America leads the world in biotechnology innovation and our industry holds great potential for advancement of the next generation of new cures and therapies for patients, as well as future economic growth and job creation. Continued advancement in biotechnology and the life sciences requires an efficient and effective regulatory environment that supports innovation, keeps pace with modern science and technology, and promotes the public health, while not impeding robust economic growth and job creation.

BIO encourages FDA's implementation of a regulatory paradigm for drugs and biologics that is guided by the principle of flexibility to account for emerging science and technological innovations. Accordingly, BIO supports an interoperable, standards-based approach to the implementation of bar code technologies that is technology neutral in regulation, and thereby allows manufacturers, who are the most knowledgeable about their products, packaging, and distribution, to determine the best suited technology or data carrier[2] for a particular product and reach industry consensus.

BIO has been supportive of the work of GS1 and EPCglobal standards development teams and many biopharmaceutical companies have utilized these standards to meet state and international track-and-trace requirements. To the extent possible, we suggest that FDA bar code regulations build upon existing GS1 standards and leverage the infrastructure already implemented to date in order to meet the dual goals of reducing the number of medication errors that occur in hospitals and other health care settings and providing adequate flexibility to address identification, validation, authentication, and tracking and tracing of prescription drugs under section 505D of the Federal Food, Drug, and Cosmetic Act (FFDCA).

II. Response to Applicable Agency Questions about the Costs and Benefits of an Alternative to the Linear Bar Code

Below BIO provides responses to questions 1-6, 10, & 12. Responses to questions 7-9, 11, & 13 are not provided, as they are solely directed to hospitals and other health-care facilities.

- ***Question One: Is there a need for alternative technologies to the linear bar code? Does the current linear bar code requirement meet the current needs of the health care industry and health care providers?***

  There is a need for alternate technologies to the linear bar code due to emerging state and federal requirements and industry business needs that promote patient safety and supply chain security and integrity. Such requirements promote processes that necessitate access to production information[3] and product specific Global Trade Item Numbers (GTINs). These processes require alternative data carriers to meet expanded data storage requirements, especially given limited label space and product size configurations.

[2] Data carrier includes linear bar codes, two-dimensional bar codes, Radio Frequency Identification (RFID), and future technologies.
[3] Production information includes lot, expiry, and serial number.

The linear bar code requirement does not meet either emerging government industry's current needs because production information and GTINs cannot always be encoded in linear bar codes due to small label sizes. Newer technologies are emerging, such as 2-D barcodes including the GS1 DataMatrix, that can accommodate more information. Businesses are now recognizing not only the business value of this new technology, but also its ability to improve the public health and patient safety.

- ***Question Two: How has product coding technology changed since FDA issued the Bar Coder Final Rule on February 26, 2004? Please provide information about the maturity, degree of adoption, cost, and ease of use of coding technologies that may be considered alternatives or in addition to the linear bar code.***

BIO recommends that FDA not require one specific bar code type but instead permit use of the GS1 approved data carriers. Using GS1 standards, manufacturers could choose the appropriate data carrier type for the package size and market. This approach would also allow for evolution when a new data carrier is accepted by the healthcare community for global use.

The emerging requirements to include production information into a data carrier will cause significant issues for manufacturers. The current linear bar code contains usually just the GTIN, which is static data, and is usually preprinted on product labels. Production information is dynamic data. In order to combine these (concatenate) two different types of data into a single data carrier, manufacturers will need to reconfigure their lines, labels, and systems.

The GS1 DataMatrix has been developed to accommodate the increasing demands for information, while reducing the footprint of the bar coded information. GS1 DataMatrix, which can encode more than 3200 data characters, allows manufacturers to include variable production information into a single data carrier, thereby reducing confusion due to multiple bar codes for downstream trading partners. GS1 DataMatrix also has improved error correction built in that enables greater readability for the supply chain. For the past 3 years, many pharmaceutical manufacturers have implemented GS1 DataMatrix in response to the California Pedigree and FDA Standard Numerical Identifier (SNI) guidance. Globally, GS1 DataMatrix is the preferred data carrier for encoding variable data on the unit of sale due to the small size of the data carrier.

- ***Question Three: What factors other than those listed in question 2 should FDA take into account in considering technologies alternative to or in addition to the linear bar code?***

Manufacturers need the ability to encode data in a standardized format for the global market. With the emerging requirements, manufacturers must have the ability to encode serialized identifiers on the unit of sale. By allowing the use of GS1's approved data carriers, manufacturers can meet most global regulations by encoding the necessary information into a single data carrier. This improves efficiency throughout the supply chain because it

eliminates the confusion and double scanning when multiple bar codes are applied to the product.

However, it should be noted that adoption of new data carriers will require a transition period where both the linear bar code and the new data carrier will co-exist to accommodate the downstream supply chain participants who need more time to convert their systems for their adoption of the new data carrier. Additionally, it is anticipated that the larger supply chain organizations will be first to adopt with the smaller organizations such as independent pharmacies following. This new technology adoption is akin to the Universal Product Code (UPC) adoption seen previously in the supply chain.

- ***Question Four: What technologies or coding systems warrant FDA's consideration as alternatives to the linear bar code? In your response, the Agency particularly invites comments on the following issues for each technology identified:***

    - ***(A) What is the current state of development and availability of the alternative technology?***

    GS1 approved data carriers (including GS1 DataMatrix and GS1 DataBar) allow flexibility while keeping the data standardized for efficient scanning and encoding. A clear and precise technical standard exists for each data carrier and allows quick adoption by all members of the supply chain. Many off-the-shelf applications are already enabled to accommodate the GS1 standards. Furthermore, because the GS1 standards are created and adopted by the industry, as new data carriers are introduced into the marketplace, the application providers and industry partners are already engaged in the implementation of the new standard.

    Any future data carrier technology will undoubtedly have unique and valuable properties for the public health and business and with this comes again new challenges of the initial investment costs, learning the new technology and implementation. All new technology needs additional development before it can be ready for broad use across the supply chain.

    - ***(B) Would adoption of this technology as an alternative to the linear bar code further reduce medication errors in hospitals and health care settings? Please provide supporting data, if available.***

    Encoding additional variable production information into the data carriers would facilitate patient safety applications, including reducing medication errors, within the healthcare community assuming: (1) the systems are programmed to act on the data appropriately, and (2) the product is not relabeled during distribution or administration.

    With the addition of variable production information, using an appropriate GS1 approved data carrier that fits the package size, the healthcare system would be able to track product by product identifier (GTIN) plus lot number, expiry date, and/or serial number. This would promote patient safety by permitting product recalls by lot number or a subset

of serial numbers associated with a lot number. Moreover, when serialization and tracking information is shared within the larger healthcare community, patient safety improves as the entire supply chain becomes more secure.

- ***(C) Would adoption of this alternative technology advance public health protections? If so, how? If supporting data exist, please provide this information.***

Utilization of these new technologies can help prevent medical errors, facilitate record keeping, reduce administration costs and improve supply chain efficiencies.

- ***Question Five: Does the adoption of this alternative technology have implications for other FDA or Department of Health and Human Services initiatives (e.g., SNI)?***

GS1 standards and data carriers have the ability to meet the emerging requirements and regulations for serialized product, including the FDA SNI guidance. For diversified companies, GS1 standards allow manufacturers to adopt one global standard to meet all of the market requirements such as Unique Device Identification (UDI) and Global Harmonization Task Force (GHTF) regulations for medical devices. Additionally, GS1 standards have been adopted globally by many countries, which results in supply chain efficiencies in manufacturing and distribution.

- ***Question Six: Have you used the linear bar code for authentication or tracking and tracing of prescription drugs?***

  - ***(A) If so, how?***

  - ***(B) Please describe any successes or challenges that you have encountered in adopting linear bar code technology for this purpose.***

  - ***(C) If not, which if any alternative technologies could reduce medication errors whole also serving other functions?***

The linear bar code has been used as the primary means of tracking and tracing case and pallet level trades between the manufacturer and wholesaler. The linear bar code does not facilitate track-and-trace or strict 100% unit-to-case aggregation because the code does not include production information.

The linear bar code restricts information to product identification only and does not provide enough granular information for tracing the product through the supply chain. Additional production information is required for authentication or tracking or tracing.

- ***Question Seven: Not Applicable***

- ***Question Eight: Not Applicable***

- ***Question Nine: Not Applicable***

- ***Question Ten: How would technology adoption have proceeded since 2004 had the bar code final rule not gone into effect?***

It is unlikely that the healthcare industry would have adopted a single standardized identification technology without direction from one or more significant stakeholders such as regulators and Group Purchasing Organizations (GPOs). Market convergence around GS1 data carriers has progressed the technology discussion since 2004.

- ***Question Eleven: Not Applicable***

- ***Question Twelve: Would there be an economic impact on those parties who may not be subject to the bar code requirement but who nonetheless may use or adopt or have adopted bar code technologies (e.g., hospitals, public health agencies, and health care providers)? Please use the following questions to guide your responses.***

    - ***(A) <u>Current practices</u>. Describe your current practice(s) at your institution with respect to those products that are required to be labeled with a bar code under [21 C.F.R.] §§ 201.25 and 610.67. Have you encountered any barriers to your ability to use technology at your institution?***

  New technologies, such as the GS1 DataMatrix, cannot be read by existing linear scanners, and therefore some products carry multiple labels, instead of one (*i.e.*, a linear bar code to satisfy current regulations and GS1 data carrier that permits transfer of production information that is required by some foreign markets and also facilitates efficient supply chain management and enhanced security). However, this dual labeling is not always feasible due to package size constraints and also builds additional inefficiencies and costs into supply chain management systems.

  Moreover, there is also an issue with the need to include human readable information, if it is not embedded in a human understandable format. Some biologic product vials and vial cartons are very small making it difficult to impossible to include both human readable information and a 2D barcode. Therefore, in certain circumstances it should be recognized that a product's numerical identifier should be machine readable only.

  While some parties who use or have adopted bar code technologies may need to invest in additional resources such as imaging scanners, and upgrade data capacity systems, only through the utilization of these new technologies can manufacturers and other members of the supply chain meet the requirements of new regulatory initiatives while at the same time help prevent medical errors, facilitate record keeping, reduce administration costs, and improve supply chain efficiencies. It is imperative that both FDA and industry adopt a standard that not only supports future growth but also recognizes and accounts for the

global nature of the supply chain and the need to adopt internationally harmonized standards.

- ***(B) <u>Using an alternative to the linear bar code</u>. If an alternative to the linear bar code could be placed on the label of at least some of your products, what impact, if any, would that have on your current practice(s)? How would you change your practices, if at all?***

Please see the discussion above.

- ***(C) <u>Expenses</u>. What unplanned expenses, if any, would you incur, if an alternative to the linear bar code could be placed on the label of at least some of your products? If you could foresee using an alternative to the linear bar code, would you modify operations in your facility, and if so, how?***

Please see the discussion above. Moreover, as capture of production information moves from manual to automatic, expenses related to dual label inefficiencies, data entry, inventory management and error correction should decrease.

In addition, any manufacturer calculation of expenses requires a clear understanding of the regulatory requirements associated with the use of bar code alternatives. We ask FDA to confirm that any change to the Bar Code Label Requirements as adopted in 2004 would not alter current reporting requirements (*i.e.*, that firms whose drug products are already approved or marketed can notify FDA about the addition of a bar code to their product labels through an annual report).

- ***(D) <u>Adverse event reporting and recalls</u>. Have you encountered challenges/successes in drug identification or reporting with respect to products that contain a bar code on their labels? If so, please describe them. Would an alternative to the linear bar code have an impact on your recall management or adverse event reporting, and if so, how?***

Administration of healthcare products currently requires the capture of the key data attributes associated with product given to a recipient, such as product identification plus production information. By using auto-identification technology to capture this information, the accuracy of the information increases. Automatic capture also provides the ability to prevent expired or recalled product from being administered to a patient, thus potentially reducing medical errors. The current linear bar code does not allow for the key additional attributes to be encoded into the single data carrier.

- ***Question Thirteen: Not Applicable***

CONCLUSION:

BIO appreciates this opportunity to comment on the "Retrospective Review under Executive Order 13563: Bar Code Technologies for Drugs and Biological Products." We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
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Biotechnology Industry Organization (BIO)