September 1, 2017

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

Re: Docket No. FDA-2017-D-2232: Product Identifier Requirements Under the Drug Supply Chain Security Act-Compliance Policy

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments to FDA's Draft Guidance entitled *Product Identifier Requirements Under the Drug Supply Chain Security Act-Compliance Policy* (Draft Guidance).

BIO is the world's largest trade association representing 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.

BIO member companies are working hard to meet the Drug Supply Chain Security Act (DSCSA) requirements to improve security of the US drug supply chain and help ensure patients are receiving authentic products. However, as was heard at the April 25, 2017 DSCSA Listening Session, readiness across the full supply chain may vary and a number of stakeholders supported an enforcement discretion period of one year. We appreciate that after hearing this feedback, FDA released this Compliance Policy on enforcement discretion for the product identifier requirements in advance of the November 2017 implementation date. In doing so, FDA provided sufficient notice to stakeholders to plan for and prepare to be compliant with the new requirements.

As we relayed at the April FDA Listening Session, without grandfathering guidance from FDA companies have had to make business decisions in order to ensure movement of product through the supply chain. Key industry stakeholders, including the manufacturers within BIO, have been operating with the understanding that the serialization obligations under DSCSA Sec 582(b)(2)(A) were tied to the date the product was packaged. That is, any product packaged on or after November 27, 2017 must be serialized while any un-serialized product packaged prior to November 27, 2017[1] could continue to be sold and distributed up to the November 27, 2019 distributor requirements.[2] A different interpretation would cause

[1] Based on the Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy draft guidance, enforcement discretion moves this date to November 27, 2018 and ties the serialization activity to transaction date and not the package date.
[2] Under this requirement, after November 27, 2019 distributors can only transact with serialized product, unless the product has been grandfathered.

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significant challenges including risk to meet statutory timelines, unnecessary cost of rework or destruction of un-serialized inventory, and the strong likelihood of shortages of critical product which will impact patient access. As such, we urge the FDA to align the Compliance Policy granting enforcement discretion to the above industry understanding.

We note that in this Draft Guidance, FDA comments briefly on its intent to issue additional guidance on the grandfathering product provisions of the DSCSA and that the guidance will address the "relationship of the compliance policy set forth in this guidance with "grandfathered" products". It is critical for FDA to issue this guidance as soon as possible so that stakeholders understand the relationship of enforcement discretion and grandfathering. Further, we ask FDA to align the compliance dates of grandfathering to the manufacturer's enforcement discretion end date which is November 27, 2018. We specifically ask that the grandfathering guidance align to the current industry understanding that any product that is packaged prior to November 27, 2018, is grandfathered from the serialization product identifier requirements. Grandfathering means these un-serialized products can be sold and distributed on and after November 27, 2018 by the manufacturer, distributor, and pharmacy for as long as the product's expiration date has not passed.

DSCSA will help improve the security of the US pharmaceutical supply chain only through the shared responsibilities and collaborative efforts across all supply chain stakeholders. Securing the US supply chain and protecting our patients from counterfeit products remain important priorities for BIO and its member companies.

BIO appreciates this opportunity to submit comments to FDA's Draft Guidance entitled *Product Identifier Requirements Under the Drug Supply Chain Security Act-Compliance Policy*. We would be pleased to provide further input or clarification of our comments, as needed. We look forward to working with the FDA to develop the 2023 vision and the path to compliance.

Sincerely,

/S/

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/S/

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