Biotechnology Innovation Organization

January 26, 2018

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

Re: Docket No. FDA–2017–D–6526: Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Draft Guidance For Industry

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA or Agency) for the opportunity to submit comments on FDA's Draft Guidance for Industry "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier" (Draft Guidance).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 and its member companies continue to work to meet the important requirements of the Drug Supply Chain Security Act (DSCSA). We are engaging in discussions regarding implementation and future visions within BIO, with other Stakeholders, and at FDA public meetings and workshops. Our members are committed to ensuring the US drug supply chain is secure, patients are receiving authentic products, and legitimate medications continue to move through the supply chain without unnecessary delays.

As we have articulated in previous FDA meetings and comment letters[1] the use of the package date for determination of whether an un-serialized product would be grandfathered is an integral piece of ensuring a smooth transition under DSCSA from un-serialized to serialized inventory within the supply chain. Another key component of this is the ability for these products to be sold and distributed until the product has reached its expiration date.

As a result, we are pleased to see this Draft Guidance interprets that a product is "in the pharmaceutical distribution supply chain" if it "was packaged by the product's manufacturer before November 27, 2018" (lines 122-124). We are also pleased that the Draft Guidance asserts that these products are "exempted as grandfathered per the

[1] Including to FDA Docket No. FDA-2017-D-2232: Product Identifier Requirements Under the Drug Supply Chain Security Act-Compliance Policy, September 1, 2017

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6301 F
bio.org

conditions of the grandfathering policy until product expiry, regardless of when the transaction occurs."

We thank FDA for listening to Stakeholder concerns regarding implementation of the grandfathering provisions of the DSCSA and releasing a Draft Guidance that will help to ensure a lower impact on movement of legitimate product through the supply chain through the use of the package date and ability to transact through expiration.

Finally, BIO appreciates that the Draft Guidance includes language regarding the use of the transaction statement as an indication that a product is grandfathered, "If the transaction information or transaction history does not include a sale before November 27, 2018, and absent other indicia that a product may be suspect or illegitimate, the transaction statement is one indication that the product was in the pharmaceutical distribution supply chain before that date" (lines 159-162). Once again the inclusion of this information in the Draft Guidance will allow legitimate product to continue to move through the supply chain and help negate any potential issues while Stakeholders begin implementing the serialization requirements.

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 comment on the Draft Guidance for Industry "Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier." We look forward to continuing to work with FDA and other Stakeholders on implementation of the DSCSA provisions and would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Cartier Esham, Ph.D.
Executive Vice President, Emerging Companies Section & Vice President, Science & Regulatory Affairs
Biotechnology Innovation Organization

/S/

Victoria A. Dohnal, RAC
Senior Manager, Science & Regulatory Affairs
Biotechnology Innovation Organization