



November 14, 2016

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

Re: Docket No. FDA-2016-N-2673: Public Meeting on Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments regarding FDA's Public Meeting on Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act (DSCSA).

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 is an active member of the Pharmaceutical Distribution Security Alliance (PDSA) and would like to reinforce and echo the positions put forth during their presentation at the public meeting and their additional written docket submission. As with our preparation for the 2015 interoperable exchange of information requirements, BIO members are working hard to prepare for the 2017 serialization requirements; however, we note that readiness across the supply chain to meet these requirements may vary.

Based on our experiences with the 2015 requirements, we note that while FDA guidance is often helpful, it is extremely important for this guidance to also be timely. If guidance is released close to the statutory requirement deadlines, individual companies and their trading partners will have instituted procedures and policies to meet the requirements that could be badly affected if the published guidance is not consistent with what has been planned or implemented. To this end, BIO notes that guidance on grandfathering, exceptions, exemptions, and waivers has not yet been released. PDSA understands that any product packaged by a manufacturer prior to November 27, 2017 or repackaged by a repackager prior to November 27, 2018 is grandfathered. At this point in time, any FDA guidance that is counter to this interpretation would likely cause significant disruption of legitimate product availability as of November 2017.

While we understand that FDA has largely been in "listening mode," gathering information on the progress that supply chain stakeholders have made in implementing the various DSCSA requirements, it will be extremely important for FDA to move to a position of dialogue with stakeholders, especially as it relates to the 2023 requirements, as it will be important for stakeholders to understand what FDA believes will be feasible and acceptable.



Additionally, it will be critical for stakeholders to hear FDA's vision of the 2023 expectations so that trading partners can have conversations guided by clarity regarding what the FDA expects 2023 to look like. These conversations will need to begin early on and decisions will need to be made far in advance of the statutory implementation deadlines.

Implementation of the 2023 requirements without dialogue between industry partners and FDA, feedback, and collaboration would create significant impediments to successful implementation. As such, we ask FDA to discuss its expectations for the 2023 system with the broader supply chain stakeholders to ensure that the conversations on this topic are constructive and in line with FDA thinking on the topic.

BIO appreciates this opportunity to submit comments regarding FDA's Public Meeting on Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Cartier Esham, Ph.D.
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Vice President, Science & Regulatory Affairs
Biotechnology Innovation Organization