PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

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To: Division of Dockets Management (HFA-305)

From: Pharma & Biopharma Outsourcing Association

Subject: Comments for Docket #: FDA-2016-N-2673: Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

Date: November 9, 2016

The Pharma & Biopharma Outsourcing Association (PBOA), a non-profit trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (collectively described as CDMOs for purposes of this letter), appreciates the Food and Drug Administration's (FDA) efforts and goals to encourage continuous improvement within the pharmaceutical industry and supports initiatives that possess potential benefits for industry, for patients, and for the FDA. To ensure clear understanding of the role of CDMOs in the supply chain, we believe that a number of items must be addressed in response to the FDA's Public Workshop for "Progress Toward Implementing Product Identification Requirements of the Drug Supply Chain Security Act" and before the FDA's draft "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information" is enacted in final form. The PBOA would like to thank the FDA for this opportunity to comment. It is important to include the CDMO voice in processes like this, as industry research from PharmSource Information Services indicated that 45% of NDAs approved in 2014 utilized CDMOs. The comments below represent a majority view of participating PBOA members who share a unique perspective as organizations providing critical services and solutions within the pharmaceutical industry. Specific or differing views may be separately presented by individual member companies in their own docket submissions. For clarity, a CDMO is not a license holder within the context of this response.

Clarity on Roles/Responsibilities

One of the foremost areas requiring clarification from PBOA's perspective is how CDMOs' manufacturing facilities are to be defined under the guidance. The draft guidance does not specifically identify CDMOs and their role in the supply chain. We request that CDMOs are not considered part of the Supply Chain. This would be consistent with current contractual arrangements between CDMOs and their clients (i.e., generally product license holders) and other scenarios where the license holder is ultimately responsible for the release of product to the supply chain. This is further justified in that there is no transfer of ownership of product between the CDMO and license holder as defined in 582(b)(A)(i). In current contractual arrangements, the license holder owns the product at all phases of interaction with the CDMO. The current majority perspective of license holders (our customers) is that the CDMO is not part of the supply chain, as defined by the FDA. This is based upon the collective input and current operational practices of our customers.

Clarity on Product Definition

PBOA members are concerned with the definition of Product as defined under Section 581(13) of the law. The

definition states "a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)," but does not clarify further by excluding products in unlabeled or unpackaged states, or in states requiring secondary packaging activities. We note that there are specific instances where the CDMO is responsible for further secondary packaging activities that are performed before the product is considered suitable for release to the supply chain by the license holder. This approach aligns with contractual obligations and ensures each license holder (product owner) is responsible for the product before release to the supply chain.

We suggest the definition of Product be clarified within applicable guidance as "a prescription drug in a finished dosage form with final labeling and packaging completed for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution),"

Clarity on Product Identifier Deadline and Grandfathering of Product

Our members are concerned and want to align with the consensus of the license holders about the definition of how the Product Identifier will be enforced on the deadline of November 27, 2017 in section 582(b)(2)(A). The requirement states "a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce." The law further states the FDA will provide guidance on Grandfathering Product as defined in 582(a)(5). The current exchange of information as required in the law does not provide a means for trading partners to definitively identify products that can be grandfathered. For example, which product date system attribute can be used to enforce grandfathering (expiration date, manufacture date, formulation date, packing date, etc.) most effectively? We request the definition of grandfathering be clarified very soon within the FDA Guidance on Grandfathering Product. Failure to provide guidance in a timely manner will instill hardship on manufacturers to adjust current operational practices and drug product inventories to meet the deadline requirements on November 27, 2017. We further recommend the FDA establish a manageable process and system attributes to identify what product will or will not be grandfathered.

Aggregation Requirement

The PBOA members would like to communicate to the FDA that many of our customers (license holders) do not currently have plans to aggregate product in the near future. Some customers may wait until the deadline enforcement of November 27, 2023 as defined in the law at 581(g)(1)(C), while others may plan to implement aggregation in the near term. These decisions and variable implementation times may hamper the FDA's efforts to recommend more efficient means of verification of product by inference, saleable returns, the distributors' ability to receive products encoded with product identifiers, and may complicate interactions of CDMO's with multiple customers in different implementation states.

The Pharma & Biopharma Outsourcing Association appreciates this opportunity to submit our comments. We understand that the FDA needs feedback from industry regarding progress in implementing product identification requirements of the Drug Supply Chain Security Act. We hope that the comments above help illuminate specific areas of interest for CDMOs and other providers of development and manufacturing services for the pharmaceutical industry. We thank you in advance for your consideration of our requests and concerns.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

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MEMBER COMPANIES

3M Drug Delivery Systems
Alcami Inc.
Afton Scientific
AMRI
Baxter BioPharma Solutions
Catalent Pharma Solutions
Coating Place, Inc.
Confab Laboratories
Cook Pharmica
DPT Laboratories
Ei, A Pharmaceutical Solutionworks
Emergent BioSolutions
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
LSNE - Lyophilization Services of New England
Metrics Contract Services
Mission Pharmacal / ProSolus Pharmaceuticals
Patheon Inc.
Pfizer CentreOne™
Piramal Pharma Solutions
Therapure Biomanufacturing
WellSpring Pharma Services

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