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OUTSOURCING ASSOCIATION

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To: Division of Dockets Management (HFA-305)

From: Pharma & Biopharma Outsourcing Association

Subject: Comments from Pharma & Biopharma Outsourcing Association (PBOA) regarding Docket FDA-2017-D-1956: Identifying Trading Partners Under the Drug Supply Chain Security Act.

Date: October 20, 2017

The Pharma & Biopharma Outsourcing Association (PBOA), a 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. 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.

We thank the Food and Drug Administration (FDA) for the opportunity to comment on the draft guidance document, *Identifying Trading Partners Under the Drug Supply Chain Security Act*. As the next step in the implementation of the Drug Supply Chain Security Act (DSCSA or the Act), the investigation and notification processes will provide supply chain participants the tools needed to protect the public from counterfeit product, intentionally adulterated product, and other fraudulent product transactions. PBOA offers the following comments and suggestions for improvement.

The draft guidance should clearly define the role of Contract Development & Manufacturing Organizations (CDMOs) as entities generally not included in the requirements of the DSCSA.

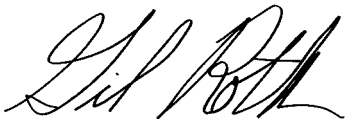
As previously communicated to the agency, much of the industry proceeded long ago with implementation based on the understanding that CDMOs do not fall within the definition of manufacturer in section 581(10) of the FD&C Act and therefore the requirements in section 582(b) of the FD&C Act would not apply. Under the statute 581(10)(A) of the FD&C act, a manufacturer is defined as *"a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;"*. CDMOs do not hold applications for product under section 505 or license for product under section 351 of the Public Health Service Act. Under the statute 581(10)(B) of the FD&C act, a manufacturer is defined as *"a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C);"*. The license holder of the product and owner of the product is the CDMO's customer (license holder) and therefore is the true manufacturer responsible for the requirements in section 582(b) of the FD&C Act. The license holder retains ownership of the product and is directly responsible for the release of the product to the supply chain and trading partners.

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)(1)(A)(i). In current contractual arrangements, the license holder owns the product at all phases of interaction with the CDMO. While CDMOs must be registered to operate under section 510 of the FD&C Act, this does not constitute ownership or control of the product being released to the market and therefore the requirements in section 582(b) of the FD&C Act do not apply. Under 581(10)(C) of the FD&C Act, a manufacturer is defined as *"(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B)."* CDMOs are not affiliates (using the common definition related to corporate ownership or control) to persons or companies that hold applications approved under section 505 or the product license issued under section 351 of the Public Health Service Act. A CDMO only provides services to a license holder (who does qualify under the definition of manufacturer of the FD&C Act). It is recommended the FDA clarify CDMOs' role by adding exclusionary content to the *Identifying Trading Partners Under the Drug Supply Chain Security Act Draft Guidance* in Section (A) and in Table 1 (e.g. Manufacturer row for column *"Entities Generally Not Included"*).

CDMOs understand these requirements are important elements to improved protection of products and patients, and they must work closely with their customers when providing contract services to ensure the requirements of the FD&C Act are met. It is important that in the provision of these services, clear lines of responsibility are understood. For example, CDMOs that perform final packaging services ensure the Product Identifier (PI) is in place for each package and homogeneous case. This includes providing the relevant PI data to the customer. This PI data allows the CDMO's customer (as the license holder) to provide the relevant transaction information, transaction history, and transaction statement as defined in 582(b)(1)(A)(i). These examples clearly show an individual CDMO's role is to assist and provide services to the license-holding customer, who has overall responsibility for the manufacture of product to ensure the requirements of the FD&C Act are met.

PBOA appreciates the opportunity to review and provide comments pertaining to the draft guidance. We look forward to FDA's continued efforts to implement the DSCSA.

Sincerely,



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