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

Re: Docket No. FDA-2014-D-0609
Draft Guidance for Industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

Dear Sir or Madam:

We submit these comments on behalf of Cook Group Inc. (Cook). Cook is a privately held group of domestic and international corporations engaged in the manufacture of diagnostic and therapeutic products for use in various medical specialties including radiology, cardiology, vascular surgery, critical care, gastroenterology, reproductive health, urology, wound care and surgery. In addition to serving these medical specialties, Cook also includes a contract biopharmaceutical manufacturer, Cook Pharmica, LLC that provides biopharmaceutical companies with a unique one-source, one-location model for development, clinical or commercial cell culture manufacturing, formulation, parenteral product manufacturing and secondary packaging. As a contract manufacturing organization, Cook Pharmica is uniquely positioned in the supply chain, interacting with a multitude of suppliers, manufacturers, and distributors.

We thank the Food and Drug Administration (FDA) for the opportunity to comment on the draft guidance document, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.* As the next step in the implementation of the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. Cook offers the following comments and suggestions for improvement.

Within the scope of the guidance document, the meaning of "product" must be clearly defined. The DSCSA defines product as "a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)." (at §581(13)) The draft guidance does not include this or any

other definition for "product." Cook recommends that the final guidance specifically include the definition of a product from the DSCSA and further clarify that a product includes prescription drugs that have been formulated into their final dosage form and packaged into their primary packaging, regardless of whether additional labeling and/or secondary packaging are necessary.

Trading partners need clear and immediate visibility to other trading partners and products that have a history of illegitimacy. Throughout Section III.A, *Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Chain*, the draft guidance recommends that trading partners use historical information about products and trading partners to assess the risks that a product may be suspect. Examples include trading partners that have previously attempted to transact illegitimate product, products that have previously been counterfeited or diverted, and firms or product that have been the subject of previous illegitimate product notifications. While these examples are all appropriate indicators that future transactions involving these trading partners and/or products should be further scrutinized, firms cannot take these factors into consideration if this historical information is not readily available in the public domain. As such, Cook recommends that FDA publish information about known and/or high risk illegitimate products and the firms involved so that trading partners can quickly identify potential risks in the supply chain.

The draft guidance should define the processes that supply chain partners are to employ to confirm that a suspect product is an illegitimate product. The DSCSA requires trading partners to quarantine suspect product and promptly conduct an investigation to determine whether the product is an illegitimate product. (DSCSA at §582(b)(4)(A) for manufacturers; draft guidance at II.A, lines 59-61) The draft guidance provides several examples of scenarios or factors that should be considered when evaluating whether a product is suspect and requires more investigation (reference Sections III.A and III.B). Beyond these considerations, however, the draft guidance does not provide any recommendations regarding the steps firms should follow to verify that suspect product is in fact illegitimate (and subject to reporting via Form FDA 3911) or cleared and fit for its intended use. The Agency should address the typical process steps that it would expect trading partners to follow during a suspect product investigation, including such factors as communication with upstream supply chain trading partners, verification of transaction histories, heightened product inspection and/or testing, review FDA's related historical illegitimate product information, documentation of investigation activities, and approval of investigation conclusions.

The reporting criteria for Form FDA 3911 need to be clearly stated, especially with respect to reports from drug manufacturers for products that pose a high risk of illegitimacy. For trading partners in the pharmaceutical supply chain, the DSCSA requires that firms notify FDA via a new form (Form FDA 3911) whenever an investigation confirms that a suspect product is illegitimate. The DSCSA imposes an additional requirement on manufacturers specifically to report cases where "there is a *high risk* that such product is an illegitimate product." (DSCSA at

§582(b)(4)(B)(ii)(II); draft guidance at section II.A, lines 71-74; emphasis added) While the draft guidance identifies a number of factors that should be considered when assessing whether a product is suspect, the guidance does not define or differentiate products that pose a high risk of illegitimacy. Without a clear definition of what constitutes a high risk of illegitimacy, as opposed to a product that is either suspect or confirmed to be illegitimate, manufacturers will be left to guess when to report. As such, FDA will find it difficult to consistently enforce this requirement of the DCSCA. Additionally, within the DSCSA, Congress provided FDA with an opportunity to identify situations that pose a high risk of illegitimacy and therefore require reporting, but the draft guidance fails to so (reference §582(b)(4)(B)(ii)(II); "a 'high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h) [Guidance Documents]."") Cook strongly recommends that the final guidance clearly articulate when a suspect product poses a high risk of illegitimacy and should be reported versus product that is merely suspect product. A practical starting point would be that a product poses a high risk of illegitimacy if it is suspect product that a manufacturer cannot reasonably confirm is not illegitimate.

<u>The final guidance must clearly differentiate illegitimate product that results from fraudulent activity versus other quality issues or product damage that may occur throughout the pharmaceutical supply chain.</u> The draft guidance (and the DSCSA) define illegitimate product to include product that "appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans." (DSCSA at §581(8)(D); draft guidance at II.A, lines 65-66) There are a number of situations throughout the supply chain that can result in a pharmaceutical product that is unfit for use and that could pose a risk to health, such as shipping damage to secondary or primary packaging, product that has been exposed to high temperatures, or lost or damaged shipping documents. While these situations can result in product unfit for use, these issues also happen routinely throughout the supply chain between legitimate trading partners and are handled through the firms' established procedures. The intent of the DSCSA and the reporting mechanism described in the draft guidance (via Form FDA 3911) is to inform FDA and trading partners of situations that involve fraud or a high risk of fraud, not every instance of shipping damage between legitimate trading partners. Therefore, the final guidance must clearly differentiate reporting of illegitimate product that does or may involve fraud versus routine shipping and handling issues between legitimate trading partners that clearly do not involve fraud.

<u>Form FDA 3911 does not clearly differentiate the Company/Facility Information of the reporter from the identification of the manufacturer, labeler, and/or distributor.</u> Form FDA 3911 includes fields for a company name and address, and the instructions for completing the form indicate that this section is where reporters would indicate "the company that is responsible for the product or for the notification." (at Attachment A, pages 11 and 15) However, since the company that is

responsible for the product (e.g., the manufacturer, labeler, etc.) may not be the company that is responsible for the notification (e.g., distributor, pharmacy, etc.), there should be distinct fields for the company information for the manufacturer/labeler and for the reporter.

Cook 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.

Thank you for considering our views.

Respectfully,

Stephen L. Ferguson
Chairman of the Board

SLF:sr