August 11, 2014

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

RE: Comments on FDA's Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Document Number FDA-2014-D-0609)

Dear Docket Officer:

The National Coalition of Pharmaceutical Distributors welcomes the opportunity to submit comments regarding the Food and Drug Administration's (FDA) Federal Register notice regarding Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Document Number FDA-2014-D-0609)

The National Coalition of Pharmaceutical Distributors (NCPD) represents and promotes the value of specialty/independent pharmaceutical distributors before legislatures, regulatory organizations, manufacturers, dispensers, and the community at large. NCPD provides a collaborative venue for its members to exchange industry knowledge, ideas and best practices to further enhance the value of the healthcare supply chain and to uphold public safety.

As the sector of the pharmaceutical supply chain with arguably the greatest level of collective experience in tracking and tracing pharmaceutical products, NCPD and its members are uniquely qualified to provide feedback and insight related to the FDA's current development of guidance this subject area. With this in mind, NCPD remains concerned that the Guidance being developed may place an unintended and/or disproportionate burden on its small distribution businesses.

NCPD believes it is imperative that the Guidance ultimately developed by the FDA does not have the unintended consequence of creating a prohibitively difficult economic environment for its members by unnecessarily creating redundant or arbitrary mandates that would impede otherwise legitimate pharmaceutical products from reaching their recipients in a timely manner.

As an example, Guidance at 1. In this section of the Guidance, "based on Agency experience with suspect product in the supply chain," the FDA identifies several scenarios involving trading partners or products "where heightened vigilance would be appropriate," including

(1) "[p]urchasing from a source new to the trading partner,"
(2) purchasing a "[p]roduct that is generally in high demand in the U.S. market,"
(3) purchasing a "[p]roduct that has a high sales volume or price in the United States,"
(4) purchasing a "[p]roduct that has been previously or is currently being counterfeited or diverted," and
(5) purchasing a "[p]roduct that has been previously or is currently the subject of a drug shortage."

While the scenarios listed above all warrant carefully screening pharmaceutical products and transactions, it is NCPD's concern that the Guidance ultimately issued by the FDA highlight that these new policies are not exploited or utilized to

hinder otherwise safe and legitimate business operations. NCPD's members routinely operate their businesses in scenarios similar to those highlighted above – while diligently working to ensure that the drug supply chain is safe and protected. We would hope that this new guidance would not be used to unfairly impede our members' transactions with their customers. Further, NCPD would welcome the FDA developing this Guidance with special consideration for the small-business participants reflected in its provisions.

Again, NCPD appreciates the opportunity to provide comments on this matter and looks forward to future discussions on this important topic. Should you have any questions or concerns related to these comments, please do not hesitate to contact me at your earliest convenience (305-690-4233).

Sincerely,

Karen L. Moody
President
National Coalition of Pharmaceutical Distributors