SUPERIOR MEDICAL SUPPLY, INC.

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2014 AUG -7 A 11:27

August 6, 2014

Division of Dockets Management (HFA-305)
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RE: Comments on FDA's Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (Document Number FDA-2014-D-0609)

To Whom It May Concern:

On behalf of Superior Medical Supply, Inc. ("Superior Medical Supply" or "Company"), this letter submits public comments on the above-referenced draft guidance ("Guidance") issued by the Food and Drug Administration ("FDA") under **Docket No. FDA-2014-D-0609**. I am the Company's contact person for this matter, so please copy me with any agency correspondence, documentation, or requests for additional information pertaining to these comments.

Superior Medical Supply is an independent or "secondary" specialty surgical distributor. Given the Company's specialized business model, it necessarily has a much smaller economy of scale than the larger, "primary" wholesalers that currently dominate the U.S. distribution market. Because of its small scale, the Company is interested in issues of both distribution security and fairness. To that end, the Company supported passage of the Drug Quality and Security Act of 2013, and the Company applauds the FDA's efforts through the draft guidance ("Guidance") to begin implementing the Act's drug tracking provisions throughout the entire supply chain.

These comments are submitted in general support of the FDA's Guidance, but with a view to whether certain provisions in the Guidance may place a disproportionate burden on small distributors like Superior Medical Supply. While most of the FDA's Guidance is intended to be non-binding, the Company is concerned that expectations created by the Guidance may in effect place a greater burden on small and independent distributors operating in the current marketplace, or create transactional prejudice by chilling their interactions with other trading partners in the market who, under the Guidance, may choose to treat virtually all transactions by secondary distributors as suspect and subject to heightened scrutiny. Or even worse, the Guidance may only serve as a pretext and further justification for the large primary distributors, including the "Big 3," to continue refusing to do business with small distributors.

These concerns focus upon the portion of the FDA's Guidance that "identifies specific scenarios that could significantly increase the risk of a suspect product entering the

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pharmaceutical distribution supply chain." Guidance at Page 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 (among other concerns)

(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."

Guidance at Pages 3-4.

While presumably unintended by the FDA, the scenarios described above typify transactions in the secondary distribution industry today, where (as explained further below) successful independent distributors must necessarily purchase their prescription drug supplies from a broad range of trading partners, and typically transact in generic medications that are in high demand, have a high sales volume or price, are often subject to protracted drug shortages, and are frequently counterfeited and/or diverted products.

This reality is part and parcel of the current dysfunctional generic pharmaceutical market. Historically, generic medications were the cheapest and most plentiful pharmaceutical products, but the generic marketplace in which most secondary distributors operate today relies upon only a small handful of drug manufacturers and is subject to frequent market disruptions and resulting chronic drug shortages. In conjunction with this market dysfunction, the FDA's Guidance will effectively require small distributors to exercise "heightened vigilance" in virtually every single drug acquisition that occurs, thereby placing a greater transactional or operating burden on small businesses to meet the FDA's stated expectations. By the same token, these expectations may prejudice the ability of secondary distributors to develop new trading partners (including larger distributors) who, under the guise of the Guidance, may decide to forego business with secondary distributors because of a perceived heightened risk or the increased effort required to engage in these transactions. These burdens and prejudices, unfortunately, may only further the anticompetitive realities of the current distribution market, wherein a mere three (3) companies control over 90% of the U.S. market.

In that regard, an additional and related concern pertains to the fact that most small distributors like the Company no longer hold the benefit of a "Big 3"/ADR distributor account as a source of supply. Historically, these large full-line distributors served as the primary source of

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prescription drugs for the secondary distribution industry. However, following a well-publicized campaign in 2011 by one of the largest U.S. hospital group purchasing organizations, and an ensuing congressional investigation in 2012 into alleged prescription drug "price gouging" by the secondary distribution industry, most of the largest distributors terminated and closed virtually all accounts held by small and independent distributors like the Company.[1] Some small distribution businesses went bankrupt during this time. The ones that survived did so by developing a much more extensive supply chain in the secondary market in order to secure adequate prescription drug supplies for their customer base.[2] This is the operational reality today for all but the largest regional secondary distributors.

As a result, most small distributors like the Company must engage in a near-constant market search for adequate drug supplies for their customers and necessarily conduct business with new trading partners on a regular basis. This reality will require "heightened vigilance" in most transactions by or with secondary distributors under the Guidance, and this burden may deter larger distributors from transacting with small distributors. In practice, the FDA's Guidance may therefore place a greater burden and prejudice upon small businesses that already face an uneven playing field in the heavily-consolidated distribution industry.[3]

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[1] These actions were contrary to representations made by the largest distributors during implementation of the Prescription Drug Marketing Act's "pedigree" requirements in approximately 2006. At that time, over the anticompetitive objections of the secondary distribution industry, the HDMA convinced the FDA to exempt all authorized distributors from pedigree on condition that these authorized distributors would continue to supply pharmaceuticals to the secondary distribution industry in the same fashion as historically. This is not the case today.

[2] The Company's experience with its customer base is typical of many small distributors. Most of the Company's customers are small in scale and lack adequate purchasing power to qualify for a Big 3 or other large ADR account. Historically, these small-scale customers relied upon secondary distributors to acquire and resell them prescription drugs from these full-line ADRs. Nowadays, these customers rely upon secondary distributors to acquire their drug supplies from other legitimate market sources at a fair price. Therefore, any prejudices or heightened expectations fostered by **the FDA's Guidance could jeopardize the already tenuous supply situation for the thousands of small medical facilities that depend critically upon the secondary distribution industry today**.

[3] With a view to the foregoing concerns, Superior Medical Supply questions the extent to which the FDA's historical "experience with suspect product in the supply chain" is instructive and should be relied upon to implement the Act. The Act will signal a new era in pharmaceutical distribution, and while transactional vigilance will remain important within the legitimate supply chain in general, implementation of the Act's provisions should draw a clear line between "authorized trading partners" and rogue entities, making it considerably more difficult for criminal enterprises to infiltrate the legitimate supply chain than before the Act. Thus, historical experiences may be of little value – illustrative or otherwise – in the new black and white reality envisioned by the Act.

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Conclusion

For the reasons explained above, Superior Medical Supply hereby requests that the FDA take notice of these comments and address them in any final Guidance to be issued in this matter, including by considering the following suggestions:

- Emphasizing that the Guidance is intended to apply to all trading partners equally and without regard to title, designation or relative scale within the supply chain.

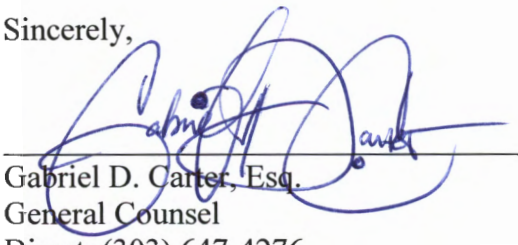
- Noting that the Guidance is intended to be utilized by all trading partners to exercise reasonable diligence on a case-by-case basis only, and should not be used to justify a blanket prohibition on doing business with certain types or categories of trading partners.

- To the extent that the FDA retains "illustrative" examples in any final Guidance, deleting the expectation of "heightened vigilance" in specific scenarios and instead stating that all trading partners are expected to exercise substantial vigilance in conducting each transaction under the Act, including but not limited to the illustrative scenarios described in the Guidance.

- To the extent that these "illustrative" scenarios are retained in any final Guidance, describing other factors in the Guidelines that also may be relevant to exercising such substantial vigilance, but which do not focus scrutiny unduly upon secondary distribution transactions, such as: (1) transactions involving narcotic drugs or other "lifestyle" drugs (such as Prozac, Viagra and other drugs that treat non-life threatening and non-painful medical or psychiatric conditions) commonly subject to abuse and diversion; (2) purchasing products from a company or individual located outside of the United States; and (3 receiving a product from any address that is different from the address of the trading partner from whom the product was initially purchased.

Superior Medical Supply appreciates the opportunity to submit these public comments to the FDA. While the Company is supportive of the FDA's efforts through this Guidance to extend and implement secure drug tracking throughout the entire U.S. supply chain, the Company would appreciate it if the FDA would address these concerns in any final Guidance.

Sincerely,



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