HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

May 25, 2018

U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Draft Guidance on Evaluation of Bulk Drug Substances Nominated For Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act [Docket No. FDA-2018-D-1067]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments on the U.S. Food and Drug Administration (FDA) draft guidance on the use of bulk substances under Section 503B of the Federal Food, Drug, and Cosmetic Act.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. We help our healthcare provider partners leverage their purchasing volume to negotiate competitive prices on healthcare products and services, helping to lower costs for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. GPOs deliver critical cost savings that allow healthcare providers to focus on their core mission: providing first-class patient care.

HSCA, its member GPOs, and our member healthcare providers are committed to protecting patients, including from poor quality or otherwise unsafe compounded drugs that could cause serious harm. However, many patients rely on compounded drugs, and 503B suppliers play an important role in helping to supply drugs that are in shortage.

Given our unique line of sight over all aspects of the healthcare supply chain, HSCA respectfully makes the following recommendations to help preserve access to compounded drugs while protecting patients from unsafe or poor quality drugs.

<u>FDA Should Reconsider Significantly Reducing the List of Approved Bulk Substances</u>

We are concerned that a significant reduction in the list of approved bulk substances for 503B compounding could lead several suppliers to exit the market, leaving hospitals, providers and the patients they serve without options for getting the drugs they need. We encourage FDA to pursue alternative methods that ensure patient safety without jeopardizing patient access to critical drugs.

1341 G Street NW, Suite 600 Washington, DC 20005 Phone (202) 629-5833 Fax (202) 466-9666
Web www.SupplyChainAssociation.org Email info@SupplyChainAssociation.org

In the event that FDA decides to move forward with a significantly reduced list, we encourage FDA to implement the guidance in phases. The implementation of this guidance will have far reaching implications for healthcare in the United States. There are safety considerations based on the likely impact to many of the ready-to-use operating room syringes. There are operational workflow considerations if these compounding activities need to be brought back into the pharmacy. There are economic considerations for the 503B outsourcing facilities which are currently performing sterile compounding with active pharmaceutical ingredients (APIs). Early notification of the approved list, with an appeal window prior to implementation, will allow the system to be able to address the potential impacts of the guidance while minimizing impact to the patients.

FDA Should Initially Inspect 503B Outsourcing Facilities Prior to Approval of 503B Status

HSCA and its members share FDA's commitment to protecting patients from unsafe compounded drugs; however, as FDA notes in its guidance, compounded drugs can play an important role for many patients who cannot use FDA-approved drugs. FDA should initially inspect all 503B compounding facilities before the facilities are approved and permitted to ship drug products into interstate commerce for human use. Additionally, routine facility inspections will ensure patient safety while also preserving patient access to compounded drugs. Inspecting facilities in a timely manner will not only help prevent contamination tragedies like the 2012 nationwide fungal meningitis outbreak, but also reduce compounding delays that can often contribute to drug shortages. It should additionally be noted that current sterile-to-sterile 503B facilities seem to have more safety issues and recalls, while other 503B facilities are operating safely, with no recalls, while employing API-sterile practices.

FDA Should Incentivize Ready-to-Use Presentations

The market is clearly providing insight into a demand for ready-to-use products. 503B facilities have ample amounts of data detailing what presentations are seeing substantial use, which could be used to incentivize traditional manufacturers to create these products. Incentivizing the creation of such products would result in an ideal circumstance where the safety of what the 503B facilities are producing is maintained but the risks associated with bulk drug substances are eliminated.

FDA Should Put Processes in Place to Ensure a Current Drug Shortage List

HSCA applauds FDA's efforts to mitigate current drug shortages and prevent future ones. As healthcare stakeholders continue to weather numerous ongoing drug shortages, timely and accurate information-sharing between FDA and all impacted parties is essential. We encourage FDA to put processes in place that utilize all available information to ensure FDA has the most comprehensive and current drug shortage list. Pursuant to that goal, we recommend that FDA update its shortage list in conjunction with other independent drug shortage lists, such as the list maintained by the University of Utah.

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We appreciate the opportunity to provide our perspective, and we look forward to continuing to work with FDA to ensure patient access to quality drugs. HSCA and its member GPOs can be a resource for FDA on compounding. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833.

Sincerely,

Todd Ebert

Todd Ebert, R.Ph.
President and CEO
Healthcare Supply Chain Association

1341 G Street NW, Suite 600 Washington, DC 20005 Phone (202) 629-5833 Fax (202) 466-9666
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