June 5, 2023

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Dockets Management
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act (Docket No. FDA-2020-D-1057)

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading healthcare group purchasing organizations (GPOs), we appreciate the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance, *"Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or Active Pharmaceutical Ingredients Under Section 506C of the FD&C Act."*

Healthcare GPOs are the sourcing and purchasing partners sto 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. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. A recent analysis found that GPOs save the U.S. healthcare system $34.1 billion annually, up to $456.6 billion over ten years, and up to $116.3 billion in Medicare savings and $90.2 billion in Medicaid savings over the same period.

GPOs allow small and rural healthcare providers – who often lack the purchasing power to access competitive pricing for essential supplies – to take advantage of the same efficiencies and discounts as larger providers. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA and its member GPOs are critical partners in averting and mitigating the impact of drug shortages – working collaboratively with hospitals, physicians, manufacturers, distributors, and government agencies to ensure that providers and patients have access to the life-saving drugs they need. GPOs track data on shortages, identify alternative suppliers, and develop other innovative solutions to safeguard access to safe, reliable, high-quality products. During the COVID-19 pandemic, GPOs helped expand capacity for critical medical supplies, including PPE, test kits and swabs, and life-saving medications by adding new non-traditional suppliers and communicating about potential demand surges.

HSCA recognizes the importance of transparency and timely communication in preventing disruptions of supply and product. The current draft guidance language states that manufacturers of covered finished products must submit a notification to FDA at least six months in advance of (1) a permanent discontinuance in manufacturing of a covered finished product, (2) an interruption in manufacturing of a covered finished product that is likely to lead to a meaningful disruption in supply of the product in the United States, (3) a permanent discontinuance in manufacturing of Active Pharmaceutical Ingredient

(API) for a covered finished product, or (4) an interruption in manufacturing of API for a covered finished product that is likely to lead to a meaningful disruption in supply of the API for the product. Given the complexity of shortages, particularly those related to supply of API, **HSCA recommends that FDA increase the advance notification period from six months to up to one year.**

The current draft guidance language recognizes that not all manufacturers will be able to adhere to the six-month notification timeline. In these cases, FDA requests that the notification be submitted no later than five business days after the discontinuance or interruption in manufacturing occurs. The difference between six months prior and five business days following a discontinuance or interruption is significant. Increasing the notification period from six months to one year will allow the Agency to have greater visibility into the potential duration, severity, and effects of a supply or product shortage.

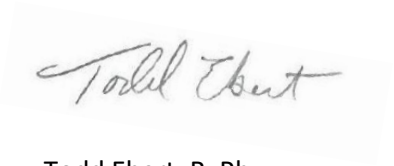
Regarding the draft guidance, FDA indicates that the March 2020 guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. **HSCA recommends FDA finalize the draft guidance well before November 7, 2023, to ensure manufacturers and applicants have a clear understanding of the information to share with FDA regarding changes in production of certain drug and biologics to help prevent or mitigate shortages of such products.**

Healthcare GPOs have served America's healthcare providers for more than 100 years. As a result, GPOs are acutely aware of the strains that shortages place on hospitals, health systems, suppliers, providers, and patients. Some shortages can be long-term, lasting for months or even years. GPOs have significant visibility into the supply chain and can provide upstream and downstream information regarding drug and product supply issues to help reduce the risk of shortages. Proactive information allows all supply chain players to manage shortages or supply issues well before they occur. **HSCA supports greater transparency and information-sharing between supply chain stakeholders and recommends that the Agency engage GPOs to ensure that all available information can be utilized in shortage prevention and mitigation efforts.**

Once FDA determines what actions to take in response to a discontinuance or interruption notification, **HSCA recommends that the Agency share their course of action and anticipated market impact with the appropriate stakeholders in a timely manner so this information can be used in contingency and risk management plans.**

We appreciate the opportunity to provide you with our perspective and we look forward to continuing to serve as a resource to our federal partners to maintain a healthy supply chain and protect access to essential drugs and products. Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



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