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December 20, 2021

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852s:

Re: Docket No: FDA-2021-D-1031

Draft Guidance for Industry - Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act

PDA recognizes and supports FDA's efforts to determine the root causes of drug shortages, to develop mechanisms to assess potential risks in the U.S. supply chain of medicines, and to mitigate and ultimately prevent shortages. The draft guidance and associated technical conformance guide (*Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide*) are helpful in defining the process for reporting the amount of listed drugs manufactured, prepared, propagated, compounded or processed for commercial distribution as required by the CARES Act addition to the FD&C Act. However, the implementation timing reflected in the draft guidance presents some significant challenges. Many sites especially at smaller firms do not have fully automated inventory management systems where such data on quantities released into commercial distribution are readily available. Or even those with such systems need time to configure a report that conforms with the formats provided in the technical conformance guide.

Although the reporting requirement originated in the March 2020 CARES Act, having the detailed requirements only in October 2021 does not provide sufficient time for all firms to comply to the February 2022 deadline for first reporting. As it may be well known, many companies are still operating with remote work settings and feeling the effects of absenteeism and other complications of the ongoing pandemic. PDA respectfully requests that the initial date of February 2022 for reporting of 2020 information be delayed or the request for 2020 data be eliminated to allow sites to develop the needed internal process for reporting of the 2021 data. In addition, PDA suggests that FDA consider the use of a tiered approach that is based on product criticality and prioritizes reporting for those products related to the public health emergency, those currently in short supply, or those drugs/biologics that are "life supporting, life sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery" as currently described in the CFR.

Industry would like to understand how the information reported will be reviewed/analyzed by the FDA (as well as any tools being developed) for the mitigation of drug shortages. A case study example would better inform industry on how the data is reviewed/analyzed and what FDA actions might occur as a result. PDA would be happy to provide a venue for FDA to make such a presentation and address any industry questions about the data submission requirements at an upcoming conference or workshop.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments have been prepared by members of PDA's Regulatory Affairs and Quality Advisory Board on behalf of PDA's Board of Directors. If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc:
Glenn Wright, PDA