PDSA
Pharmaceutical Distribution Security Alliance

1050 K Street, NW
Suite 310
Washington, DC 20001

December 8, 2014

The Honorable Margaret Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Boulevard
Silver Spring, Maryland 20993

Re: Implementation of the January 1, 2015 Requirements of the Drug Supply Chain Security Act

Dear Commissioner Hamburg:

The companies that comprise the Pharmaceutical Distribution Security Alliance (PDSA) are working diligently successfully implement the requirements of the Drug Supply Chain Security Act (DSCSA) that go into effect on January 1, 2015. PDSA is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers. More than 30 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal during implementation is ensuring that patients have uninterrupted access to safe, authentic, FDA-approved medicines. As a cross-section of the supply chain, we wish to share progress and concerns with FDA in the hopes of maintaining open lines of communication, given the critical role that the Agency played in developing the legislation, and now in overseeing implementation.

Having undertaken the enormous task of developing and setting up DSCSA-compliant systems and processes across the supply chain, we have been actively working with trading partners to conduct the necessary testing to ensure that these systems run smoothly come the new year. Significant progress has been made in recent weeks, and we expect this progress to continue. We are aware that implementation readiness cannot be achieved by a company working alone, but by the collaborative and coordinated efforts of the full supply chain.

Given the interconnected nature of the supply chain, we are encountering a large degree of uncertainty and challenge regarding January 1, 2015 implementation across all sectors of the supply chain. As with any complex process, there will be challenges, glitches, and gaps that have not been or cannot be anticipated and which will need to be addressed as they arise during the initial weeks and months. These concerns are particularly apparent with regard to: solutions providers who are encountering challenges developing new portal technology; transactions with smaller trading partners who are not capable of utilizing ASNs yet (and so must work to handle paper transaction documents); trading partners who are utilizing ASNs as a means of information exchange for the first time; lower-volume trading partners who have not yet finalized their information-sharing procedures; and supply chain participants who serve unique and under-represented populations.

PDSA members are working diligently with our customers and trading partners daily to solve problems as they arise, and we will continue to do so through the first weeks and months of 2015.

PDSA shares FDA's commitment to ensuring timely patient access to drugs and avoiding potential drug shortages resulting from unnecessary supply chain process disruptions and uncertainties. Recognizing this joint objective, the members of PDSA respectfully request that FDA establish a regular forum (face-to-face meeting, conference call, or Webex) for ongoing dialogue and continued flexibility to work with the Agency, individually and as a coalition, through critical compliance issues during the first quarter of 2015 to ensure effective implementation of the DSCSA.

Sincerely,

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cc: Dr. Ilisa Bernstein, Deputy Director, Office of Compliance, Food and Drug Administration
Dr. Connie Jung, Acting Associate Director for Policy and communications, Office of Drug Security, Integrity, and Recalls, FDA Center for Drug Evaluation and Research