



December 4, 2014

Dr. Ilisa Bernstein
Deputy Director, Office of Compliance
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 51, Rm 5271
Silver Spring, MD 20993-0002

Re: Pharmaceutical Distribution Security Alliance Questions and Answers Regarding
the Drug Supply Chain Security Act

Dear Dr. Bernstein:

On May 22, 2014 the Pharmaceutical Distribution Security Alliance (PDSA) submitted to you a set of thirteen questions not directly answered by the plain language of the Drug Supply Chain Security Act (DSCSA) and answers to those questions that PDSA believes constitute reasonable and appropriate interpretations of the statutory text. PDSA supplemented that submission with one additional question and answer on October 29, 2014. PDSA respectfully asks that the FDA provide further direction and clarity consistent with the following supplemental question and answer, which is related to the question and answer submitted on October 29, 2014.

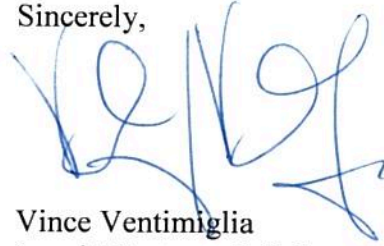
15. If a dispenser is not required to be licensed under applicable state law, how does the dispenser satisfy the requirement to be an authorized trading partner?

The DSCSA provides that a dispenser is “authorized” if it has a valid license under State law. FDCA § 581(1)(D). However, certain dispensers, such as pharmacies owned and operated by the Department of Defense and many other federal- or state-run dispensers, are not required to obtain a license under applicable State law. Transactions with dispensers, such as federal and state-owned pharmacies that are not required to be licensed under applicable state law are low risk transactions. Therefore, we ask that the Agency, through guidance or formal exemption, indicate that state or federally owned dispensers are deemed “licensed” for purposes of the DSCSA, if they are not licensed by the state.

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PDSA appreciates the FDA’s consideration of the questions and answers it has submitted. We welcome the opportunity for further discussion about these important topics.

Sincerely,



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The content and statements in this document and all enclosed documents are provided for informational purposes only by the Pharmaceutical Distribution Security Alliance, a coalition of companies and organizations dedicated to the safety and integrity of the pharmaceutical distribution supply chain. These statements are not intended as legal advice. Action on the basis of these statements should involve consultation with professional legal counsel.