PDSA
Pharmaceutical Distribution Security Alliance

October 29, 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 would like to supplement that submission with one additional question and answer included below. PDSA respectfully asks that the FDA provide direction and clarity with regard to, and consistent with, the following additional question and answer.

14. If an entity constitutes a "manufacturer" under the DSCSA (new Section 581(10)) but is not required to be registered under Section 510 of the Federal Food, Drug, and Cosmetic Act, (a) are trading partners exempt from the restriction against doing business with them because they do not have "authorized trading partner" status, and (b) if not, how does the manufacturer satisfy the requirement to be an authorized trading partner?

The situation described above is an example where the definitions and requirements under the DSCSA are not fully aligned with the requirements that already exist under the Federal Food, Drug, and Cosmetic Act (FDCA) or with the drug supply chain's business practices.

Co-licensed partners of the NDA/ANDA/BLA holder, including Private Label Distributors, clearly qualify under the DSCSA as "manufacturers" because they have a licensing or other similar business arrangement with the NDA/ANDA/BLA holder (see PDSA Q and A #6, submitted May 22, 2014). Because these establishments are not "engaged in the manufacture, preparation, propagation, compounding, or processing of a drug" they do not meet current criteria under FDCA Section 510 for obtaining an FDA establishment registration. Similarly, an NDA/ANDA/BLA holder that retains a contract manufacturer also is not subject to the registration requirement under Section 510 but does qualify as a manufacturer under the DSCSA (Section 581(10)(A)). The inability of these entities to qualify for registration under Section 510 creates a conundrum because

in order to be an authorized trading partner under the DSCSA (Section 581(2)), a "manufacturer" must have "a valid registration in accordance with section 510."

In order to address this disconnect between statutory provisions, we recommend that FDA recognize and accept each and any of the following actions as demonstration of "authorized trading partner" status for an entity that qualifies as a "manufacturer" under the DSCSA definition (including NDA/ANDA/BLA holders, co-licensed partners, affiliates of NDA/ANDA/BLA holders, and affiliates of co-licensed partners) but falls outside the scope of Section 510 of the FDCA.

1. The company has a valid Labeler Code under 21 C.F.R. § 207.20(b), and places its own National Drug Code (NDC) number, with the FDA-assigned Labeler Code, on the label; **OR**

2. The existence of a co-licensed partner agreement between the application holder and the company under which both the application holder and co-licensed partner (or its affiliate) are identified by name on the product label (*e.g.*, the label states "manufactured by [*application holder's name*] and distributed by [*co-licensed partner's/affiliate's name*]"); **OR**

3. An attestation from the company that qualifies as a manufacturer under the DSCSA to its trading partner which states (a) that it is the NDA/ANDA/BLA holder, an affiliate of the NDA/ADNA/BLA holder, or a co-licensed partner of the NDA/ANDA/BLA holder, and (b) that it is not required to register its establishment under section 510 of the FDCA because it does not manufacture, prepare, propagate, compound or process the drug.

Each of these options, individually, provides evidence to potential trading partners of a company's standing as "authorized" even though the company cannot be registered under Section 510 of the FDCA.

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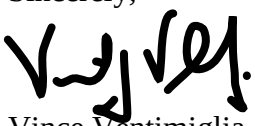
PDSA appreciates the FDA's consideration of this additional question and answer. We welcome the opportunity for further discussion about this important topic.

Sincerely,



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