



Vince Ventimiglia

Principal

FaegreBD Consulting

1050 K Street NW, Suite 400

Washington, D.C. 20001-4448

Direct: 202-312-7463

Vince.ventimiglia@faegrebd.com

May 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: Abbreviated Transaction Statements Under the DSCSA

Dear Dr. Bernstein:

As you know, the Pharmaceutical Distribution Security Alliance (PDSA) is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. More than 30 companies are formal members of PDSA (a membership list is enclosed), while many other external stakeholders provide additional policy and technical support. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

As you also know, the Drug Supply Chain Security Act (DSCSA) requires a trading partner transferring ownership of a product in a transaction to provide the subsequent owner with a transaction statement. The term “transaction statement” is defined in section 581(27) of the FDCA.¹

In our comments submitted to Docket No. FDA–2014–N–0200 on April 17, 2014, we noted the challenges trading partners would face in providing an unabbreviated version of the transaction

¹ The transaction statement applies only to products that are within the scope of the DSCSA. This letter does not address the direct purchase statement required for certain trading partners under Section 582(c)(1)(A)(ii)(I)(aa)(AA). The direct purchase statement raises questions that PDSA members continue to evaluate.

statement that fully recites, on a transaction-by-transaction basis, each individual clause enumerated in the statutory definition of a transaction statement. Many of our members also highlighted this challenge in the comments they submitted individually. We write separately here to emphasize the significance and urgency of this issue.

We are aware that at least one of our members, the Healthcare Distribution Management Association, has proposed to the FDA language for an abbreviated transaction statement. PDSA submits the following proposed abbreviated transaction statement for your consideration, which is the consensus-based proposal approved by our membership:

[COMPANY] has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G).

Or

Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G).²

We believe that this proposed abbreviated transaction statement complies with the statutory requirement to provide a transaction statement, meets the spirit of the law, and provides the operational flexibility necessary to allow trading partners to provide transaction statements in an efficient and economical manner.

A requirement that trading partners provide an unabbreviated transaction statement that fully recites each individual clause in the statutory definition of a transaction statement would be unduly burdensome and would not provide added value.

First, the size of an unabbreviated transaction statement would be unduly burdensome for trading partners. For example, many trading partners will rely on advance ship notices (ASNs) or paper packing slips to meet the January 1, 2015 requirements related to providing transaction statements. Given the nature of these documents, it will be very difficult as a logistical matter to include an unabbreviated transaction statement. The transaction statement field on an ASN, for example, simply does not accommodate enough characters for inclusion of an unabbreviated transaction statement. Space is similarly at a premium on paper packing slips.

The abbreviated transaction statement proposed above is approximately 500 characters shorter than a full, unabbreviated transaction statement (80 characters compared to approximately 580 characters). Therefore, with regard to electronic transaction statements, more than seven times as much storage would be required if unabbreviated transaction statements were required. This carries a very real cost for industry.

² Some of our members prefer to use the word “Seller” in lieu of the company name because the name of the company transferring ownership of the product would already be available in the transaction information provided. For example, when using the Electronic Data Interchange (EDI) method for transmitting the transaction statement, the company name is reported in a different line in the 856 Advance Ship Notice (ASN).

Second, an unabbreviated transaction statement is unnecessary and would not add value. The statutory reference included in the abbreviated transaction statement proposed above fully incorporates all of the statutory elements of a transaction statement. Reciting the specific statutory text referenced by the abbreviated transaction statement would not add any value to trading partners, the FDA, or other stakeholders because the full scope of that statutory text is incorporated into the abbreviated transaction statement by reference.

PDSA respectfully asks that the FDA expressly acknowledge the acceptability and appropriateness of using an abbreviated transaction statement and specifically asks that the FDA acknowledge the acceptability and appropriateness of the abbreviated transaction statement proposed above as an example that a company could follow in formulating its transaction statement. We have noted in our prior response to the Agency's Request for Information regarding the interoperability of exchange standards, that supply chain stakeholders generally will need a full six months in order to establish, test, and initiate the systems required to effectively exchange information with trading partners. Accordingly, we are concerned that failure to approve the use of an abbreviated transaction statement by July 1, 2014 will cause continuing uncertainty within industry and will force trading partners to implement systems for providing transaction statements without the benefit of assurance that the systems being implemented will be consistent with the FDA's interpretation of the DSCSA requirements related to transaction statements.

PDSA looks forward to collaborating with the FDA to ensure that an abbreviated transaction statement necessary to meet the operational realities faced by industry is consistent with the FDA's understanding of the statutory requirements. We greatly appreciate the FDA's consideration of this issue, and we welcome the opportunity for further discussion of this important topic.

Sincerely,

A handwritten signature in black ink, appearing to read "Vince Ventimiglia". The signature is stylized and cursive, with a period at the end.

Vince Ventimiglia

The content and statements in this document 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.