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FDA Issues DSCSA Annual Reporting Guidance for 3PLs

The Food and Drug Administration ("FDA") has released preliminary guidance governing annual reporting by 3PLs as required under the Drug Supply Chain Security Act of 2013 ("DSCSA"). This guidance will affect 3PLs that are warehousing or providing "other logistics services" for prescription drugs in interstate commerce on behalf of a regulated manufacturer, wholesale distributor, or dispenser. Under the DSCSA, 3PLs are required to provide FDA with facility specific information including its name, state licensure information (if any), basic facility information, and all trade names under which it conducts business. FDA is also requesting reporting of additional information beyond what is required by the DSCSA, including the reporting of significant disciplinary actions by any state or federal agency. FDA intends to make reported information about 3PLs publically available on FDA's web site.

The DSCSA defines the term "third-party logistics provider" to mean "an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product."

With respect to the obligation to report state licensing information, the requirement only applies if state currently requires licensing. Eventually, FDA is required by the DSCSA to establish its own licensing regulations for 3PLs by no later than November 27, 2015. Once those licensing regulations are in place, 3PLs will need to be licensed by FDA or through an accreditation program approved by the FDA.

Initial reports by 3PLs are due by March 31, 2015. The FDA Guidance is ambiguous as to whether all of a 3PL's facilities need to be reported, or only those from which drugs are distributed, but when read in conjunction with the governing statute, it would appear that reporting is only required for those facilities from which drugs are being distributed. Ideally, the FDA will provide additional guidance to clarify this point.

Reporting can be done through FDA's portal at www.fda.gov/wdd3plreporting or by contacting FDA by email at WDD3PLRequirements@fda.hhs.gov if you wish to utilize an alternative reporting method. 3PLs reports are due by March 31, 2015.

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