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Mandatory Adverse Event Reporting: Retailer Responsibilities

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In 2006 the mandatory adverse event (AE) reporting legislation known as the *Dietary Supplement and Nonprescription Drug Consumer Protection Act* was enacted and became law. The legislation, which had been strongly supported by industry, carried specific language identifying various roles and responsibilities for those that would be subject to the new regulations. With industry input, the authors of the legislation understood the unique characteristics related to the sales and marketing of dietary supplements including marketing partnerships, and private labeling practices and sought to clarify exactly who was responsible for receiving, documenting, evaluating and, when required, reporting of serious adverse events (SAER's) to the FDA. The law specifically identified the responsible party for reporting of SAE's as the manufacturer, packer or distributor of the supplement, whose name appears on the label.

Retailers were singled out in the legislation as entities likely to be notified by consumers wishing to report AE's. If the retailer's name is not on the product, they have no documenting, reporting, or record keeping obligations regarding AE's, but if their name is on the label it sets in motion a whole process for meeting regulatory obligations on their part that can take a number of paths to compliance.

For those retailers with their name on the product label, Congress understood that the retailer may not have the necessary expertise, personnel or adverse event documentation systems to manage AE reporting obligations so provisions were offered that allowed those retailers to establish alternative measures to ensure AE documentation and reporting of SAE's. In fact, they were not exempted from reporting responsibilities but were specifically instructed to either assume full responsibilities themselves or establish reporting agreements with other responsible parties as follows:

(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 403(y).

Even in those circumstances where there is an agreement in place for the retailer to delegate reporting responsibilities to others, the retailer must ensure that there are specific standard operating procedures (SOP's) in place related to how adverse event reports are referred upstream to the packer or manufacturer. This would include training of retail employees that would reasonably be expected to learn of AE's from consumers. They must understand the adverse event reporting obligations of the retailer, know what an adverse event is (ie. "*The term 'adverse event' means any health-related event associated with the use of a dietary supplement that is adverse*") and how they should advise the consumer regarding referral of reports to the responsible party. Typically, consumers would first be advised of the opportunity to report their adverse event and then referred to the proper reporting channel which often times is the specific company phone number displayed on the product label. Use of FDA's MedWatch number on product labels in lieu of a company specific phone number is strictly prohibited. Depending on consumer communication channels established by the responsible party, consumers might also be able to report their AE to the responsible party through email or social media such as the responsible party's Facebook page. This is important as the regulations require documenting reports of adverse events from all methods of communication, written or verbal.

Private label contract manufacturers also have a role in helping their customers put appropriate adverse event management programs in place. They must remind their customers of their regulatory reporting obligations and make sure there is a clear understanding regarding who is responsible for what. This is especially important since contract manufacturers are usually responsible for GMP compliance and investigating AE's to ensure there is not a GMP issue requires good communication between both parties.

If the retailer's name is on the label there are a few tips to keep in mind that can help streamline the process;

1. Establish written agreements: A clearly written agreement or memorandum of understanding should be developed specifically identifying who is responsible for what. It should include methods of transmitting reports or directing consumers to appropriate reporting channels. It should also delineate how information will be shared between parties in the event of product issues such as GMP specification breaches.
2. Establishing standard operating procedures: Even if your contract manufacturer or packer assumes responsibility for adverse event reporting, the retailer employees must know how to get the reports to them. They also must have a basic understanding of the retailer's regulatory obligations in this regard so they can facilitate reporting through the proper channels.
3. Conduct an annual compliance audit: Although not required, it's a good idea to conduct an internal audit on an annual basis to make sure events are being managed appropriately especially since the retailer cannot delegate all of their liability to the manufacturer. If reports are not being documented and/or reported to the FDA within the 15 business day window, both parties may be subject to citations, and other sanctions by FDA. Either or both parties could even lose insurance coverage if their carrier was not apprised of SAE's and a litigation issue subsequently arose.

In the event the retailer chooses to shoulder all the adverse event reporting obligations themselves, they will need to put in place a robust surveillance system to document all events, apply appropriate medical judgment to determine which events meet the serious criteria, and ensure all SAE's are submitted to the FDA within the allowed reporting timeframes.

The FDA has recently stepped up enforcement regarding AE compliance for all responsible parties and issued 483 citations, warning letters and applied other sanctions. For those retailers with private labeled products bearing their name, proactively reviewing roles and responsibilities between all parties will help ensure full regulatory compliance.