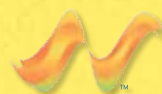


LEGISLATIVE UPDATE!



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New Rules on Private Label Products!

Retailer Responsibilities and Liabilities Under the Proposed “Dietary Supplement and Nonprescription Drug Consumer Protection Act”¹ (also known as the “AER Bill”)

Congress is considering legislation that will treat dietary supplements like drugs for adverse event reporting. This legislation also imposes significant new responsibilities and liabilities on retailers of dietary supplements. If passed, it will increase your regulatory burdens and may place some ingredients and your private label products at risk. What should you be aware of? You will have significant notification and recordkeeping responsibilities for private label products. These include:

Label change requirements. Your private label products will need to include an address or phone number through which a person may submit a report of a serious adverse event.² If you use your own address or phone number, you will need to make sure reports are properly received and documented and then forwarded to FDA or your co-packer. Your labels could alternatively include the address or phone number of the co-packer for receiving these reports.³

A 15-day reporting requirement to FDA for serious adverse events. The Act requires a retailer whose name appears on a dietary supplement (a private label product) to report all serious adverse events to FDA within 15 days of learning about the event. The Act also requires manufacturers to report serious adverse events to FDA. Note that some manufacturers have decided to report all adverse events to FDA—both serious and non-serious.

A recordkeeping requirement for all complaints. You must keep records related to both serious and non-serious adverse events (medical complaints) for six years.

Reporting obligation can be transferred to co-packers. You may enter into a contract with each co-packer of private label products to transfer the reporting obligation to FDA, but *only if* you report *all* adverse events (not just the serious events) associated with the product to the co-packer. The co-packer then has to determine which, if any, of these adverse events qualifies as “serious” and report those to FDA within 15 days (unless the co-packer decides just to report all of them to FDA).

Even with a reporting arrangement, there are additional issues to consider, including:

Capturing consumer information. You may wish to establish systems and training for staff to ensure the prompt capture of all information given by a consumer who notifies a store of any kind of medical or health complaint that is associated with your private label dietary supplement.

Prompt notification of FDA or your co-packer. If you are reporting to FDA, you must submit reports of serious adverse events to FDA within 15 days. If you negotiate a reporting arrangement with your co-packer, you must report all pertinent information immediately to the co-packer. As a retailer, you want to avoid letting the FDA, a plaintiff lawyer or even a co-packer claim that you waited too long to notify the co-packer.

Strict recordkeeping. You may wish to establish systems to document the date and manner in which you notified FDA or the co-packer (including the name and contact information of the person to whom you transmitted the information) and precisely what information was transmitted.

¹All references to the Act are to the latest version, a copy of which is available at www.nutraceutical.com/new.

²“Serious adverse event” is defined as “an adverse event that results in death, a life-threatening experience, in-patient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent” one of these outcomes.

³This of course takes you out of the loop, which you may wish to avoid if it is your product. Also, consider that if you use more than one co-packer, it may mean your labels have different numbers and addresses for each co-packer, which may be confusing to customers. This would also mean that each time you change co-packers, you would need to modify your label with the new address and/or phone number. One significant question is whether your co-packer is willing and able to receive and handle consumer calls or letters, particularly if they are manufacturing the product to your specifications.

Product retention policy. You may wish to implement a system to ensure that you have retained a sample of each batch of a private label product. This will help you demonstrate whether or not any product issues occurred before or after delivery to the store or the consumer. You will also need to carefully track and retain any product returned by the complaining consumer. These samples should be saved for at least six years.

Document retention policy. You are required to keep all records related to complaints for at least six years. If product liability litigation or a government investigation later occurs over your private label product, you need to be able to prove that you complied with the Act.

Tracking batches and co-packers. You should exercise particular caution if you change co-packers or if a co-packer goes out of business. What happens if you receive a product complaint and have switched co-packers? Do you call the prior co-packer (who may be upset after the relationship was terminated)? Or your current co-packer? Do you have a way of knowing which co-packer manufactured a specific bottle?

Monitoring compliance by co-packers. You may wish to follow-up with your co-packer to ensure they have filed all required reports with FDA. For example, if your co-packer goes out of business, you may need to file a report yourself.

Additional Issues for Branded Dietary Supplements:

How to handle adverse events from branded products supplied by other parties. The Act does not require you to notify or report adverse events associated with branded dietary supplements supplied by other parties, but the reporting requirements imposed on these suppliers may indirectly create some concerns for you. For example, if one of your customers calls to complain about an adverse event due to a branded supplement you sell, is it appropriate to simply ignore the call? How can you explain to a court or FDA that you did nothing? What if other consumers are also subsequently injured? You may wish to treat this call as if it were a report about one of your own private label products and promptly notify the manufacturer. If you decide to notify the manufacturer, you may wish to document the fact that you notified the manufacturer, including the name of who you spoke to and the details of what you provided. This information may be important later if litigation occurs. You may wish to keep it for six years to protect yourself. In short, you may find it best to treat all dietary supplement products—both private label and branded—as if they were private label products.

What are the consequences of non-compliance?

Non-compliance may be a crime. Failure to comply with labeling requirements is an act of misbranding. See 21 USC 331. The Act amends 21 USC 331(e) to make it a violation of the FDC Act to refuse to permit FDA access to any of the records you retain. It is unclear what charges might be brought if you fail to report on time or keep required records. A prosecutor might argue that one or more of these failures is a violation of 18 USC 1001(a)(1), which makes it a felony to intentionally conceal a material fact.

In lawsuits, product liability lawyers may conduct discovery to determine if you were in compliance with the Act and, if you weren't (or can't demonstrate you were in compliance), these lawyers may be able to create a presumption or inference that you were negligent. This may weaken your defense.

Is this Legislation Really Needed?

We do not believe the Act is necessary or that it will help consumers. Unfortunately, since our trade associations don't have to live with the consequences of the Act and haven't heard many objections, they haven't opposed it. At this point, passage of the Act is in the hands of senators and representatives and is almost certain.

What has Nutraceutical done?

Nutraceutical has done its best to protect consumers and the industry. Among other things, Nutraceutical previously distributed a brochure to our health food store retailers entitled *Adverse Reactions to Foods and Dietary Supplements: Answers to Common Questions*. We distributed one million copies because many industry participants and critics seem unaware that there is an existing adverse event reporting system. We believe the existing system is adequate and the only change needed may be additional funding for this system. We have spent many hours writing letters, organizing seminars, and meeting with trade associations and with senators and representatives. We have managed to request and obtain significant changes and improvements to the Act, but we remain very concerned about its consequences for consumers and our industry.

What Can I Do About this Legislation?

Contact your senator and/or representatives. If you wish to object to the Act, or think that changes to it are needed, please contact your senator and/or representatives and voice any concerns. To view a copy of the Act, our AER brochure, a summary of concerns about the Act and instructions for contacting your senator and/or representatives, please visit www.nutraceutical.com/new.

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