

Being a Member Simplifies Regulatory Compliance

Accurate Adverse Event Reporting

How SafetyCall® can help you through FDA's new guidance

Recently, FDA issued its final guidance on Serious Adverse Event (SAER) reporting and record keeping as it pertains to dietary supplements. The first draft of this guidance was issued in October 2007 and, after considering comments from consumers and other interested organizations, the agency made minor changes, and issued the final guidance. Manufacturers of dietary supplements may be wondering what it means to them and what their obligations are as they relate to the law. Here are a just a couple initial considerations for NPA manufacturers regarding a potential FDA audit:

- Do you have a system in place to receive, document, assess for seriousness, and report on an FDA form 3500a within 15 business days (with hard copies of pertinent labeling) those incidents that meet the FDA's specific criteria for reporting eligibility?
- Is your system designed to not only document all incidents (serious and non-serious), but are these adverse event reports also being stored for the required six-year archive period, for retrieval at a moment's notice by your friendly FDA compliance officer who will want to review all, some, or select incidents to insure compliance?

Understandably, FDA compliance officers want to be confident that, if consumers use your product and contact you regarding an unintended effect, you will have systems in place to ensure their voice is heard and, if applicable, is relayed to FDA. To this end, your system needs to document who's calling, what product they were using, what adverse effects they experienced, what was the medical interpretation of level of seriousness (per FDA classification criteria of serious or non-serious) and, if serious, was the incident reported to FDA.

It can get complicated, but the good news is SafetyCall is here to help. Using our program, Natural Products Association members can put in place a turnkey system to ensure that they are meeting both the letter and intent of the law. SafetyCall experts have the expertise FDA encourages companies to use to meet their reporting obligations. As a trusted NPA partner, SafetyCall will help companies meet regulatory reporting requirements as well as sup-



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of the law, but in some cases, FDA also reached a different conclusion based on the information (or lack of clear information) shared with them. FDA can only draw conclusions based on what you give them. If the reports are incomplete, inconsistent, poorly documented, riddled with layman terms that FDA medical professionals will find unsettling or vague, then you can expect concerns to be raised.

AER reports should answer questions, not raise them. To that end, it can only benefit you to engage the experts at SafetyCall to help you add context to reports so you can accurately reflect the safety of your products. Contact SafetyCall or NPA today to find out more about how we can help you. ■

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port good product stewardship and safety.

Recent high profile FDA actions have not only involved cases where someone didn't record or report adverse events to meet the letter

