

# As an NPA Member and a New Client of Safetycall You Receive Reduced AE Management Services!

## Why is Adverse Event Management Important?

In 2009, the FDA issued guidance on Serious Adverse Event Reporting (SAER) and record keeping as it pertains to dietary supplements. The law sets forth certain obligations of dietary supplement manufacturers for monitoring, documenting and reporting adverse events to the FDA. It's important that manufacturers understand what is expected, so you are in compliance with the law. To gauge whether or not your company is prepared for a potential FDA audit, ask these questions:

- Do you have a system in place to receive, document, assess for seriousness, and report incidents that meet the FDA's criteria for reporting, within 15 business days?
- If you have a system, does it document all incidents considered serious and non-serious? Are those records retained for the FDA's required six-year archive period, and retrievable at a moment's notice should an FDA compliance officer need to review all, some, or select incidents to ensure compliance?

FDA compliance officers want to be confident that if consumers contact you regarding an unintended effect,

you have a system in place to track incidents, and if applicable, relay them to the FDA. Systems need to document who called, what product they were using, what adverse effects were experienced, what the medical interpretation of the level of seriousness

was (per FDA classification criteria of serious or non-serious), and whether or not incidents were reported to the FDA.

The FDA can only draw conclusions based on what you provide them. If the reports are incomplete, inconsistent, poorly documented, or riddled with layman terms that FDA medical professionals find unsettling or vague, concerns will be raised. Adverse event reports should answer questions, not raise them.



It can get complicated, but the experts at SafetyCall simplify the process. We work with NPA members to put turnkey systems into place that ensure you are meeting both the letter and intent of the law. Our experts will ensure you are in compliance and that your reports accurately reflect the safety of your products.

As a trusted NPA partner, SafetyCall helps clients with adverse event regulatory reporting, as well as managing systems for good product stewardship and safety. Contact SafetyCall [here](#) to find out more about how we can help you.

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