

# Nutritional & Dietary Supplements



## Industry Obligations

Nutritional and dietary supplement registrants must also consider the following compliance obligations:

- Be wary of incorrect assumptions! Industry executives mistakenly assume that their products are inherently safe because dietary supplements are considered “natural” and do not contain “synthetic ingredients.”
- Understand that consumers will most likely report adverse events directly to the manufacturer. This means that manufacturers need to implement additional processes for differentiating between those adverse effects with may represent a potential safety concern for those having nothing to do with the use of the product.
- Be aware of background noise involving adverse events not related to product use.
- Causality is **not** a prerequisite for tracking and reporting adverse events associated with the use of Dietary Supplements.

## SafetyCall Dietary Supplement Services

Two regulations applicable to the Dietary Supplement industry that are a focus of SafetyCall services are highlighted below:

### Dietary Supplement & Nonprescription Drug Consumer Protection Act:

Under federal law distributors, manufacturers and packers of dietary supplements in the US must report medical problems that are associated with their products.

Firms are required to document and assess adverse events based on “reasonable medical judgment.” Adverse events meeting the FDA defined criteria for **serious** must be reported to the FDA within 15 business days using the FDA form 3500A and its accompanying data elements.

Serious adverse events may include, but are not limited to, the following: “death,” “a life-threatening experience,” “inpatient hospitalization,” “a persistent or significant disability or incapacity” or “a congenital anomaly or birth defect.”

### Canadian Food and Drug Act—Natural Health Products Regulations:

Serious adverse reactions must be reported to Health Canada within 15 days. Manufacturers must prepare Annual Summary reports that include a critical analysis of the adverse event data reported for natural health products sold in Canada over a 12 month period.

Contact SafetyCall today to learn more about services we provide to the Dietary Supplement industry.