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21 U.S. Code § 379aa-1

Serious adverse event reporting for dietary supplements

(a) Definitions

In this section:

(1) Adverse event

The term "adverse event" means any health-related event associated with the use of a dietary supplement that is adverse.

(2) Serious adverse event

The term "serious adverse event" is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(3) Serious adverse event report

The term "serious adverse event report" means a report that is required to be submitted to the Secretary under subsection (b).

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