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21 U.S. Code § 379aa

Serious adverse event reporting for nonprescription drugs

(a) Definitions

In this section:

(1) Adverse event

The term "adverse event" means any health-related event associated with the use of a nonprescription drug that is adverse, including—

(A) an event occurring from an overdose of the drug, whether accidental or intentional;

(B) an event occurring from abuse of the drug;

(C) an event occurring from withdrawal from the drug; and

(D) any failure of expected pharmacological action of the drug.

(2) Nonprescription drug

The term "nonprescription drug" means a drug that is—

(A) not subject to section 353(b) of this title; and

(B) not subject to approval in an application submitted under section 355 of this title.

(3) 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).

(4) 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).