

21 U.S. Code § 364a

Adverse events

(a) Serious adverse event reporting requirements

The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.

(b) Submission of reports

(1) Serious adverse event report

The responsible person shall submit to the Secretary a serious adverse event report accompanied by a copy of the label on or within the retail packaging of such cosmetic product no later than 15 business days after the report is received by the responsible person.

(2) New medical information

The responsible person shall submit to the Secretary any new and material medical information, related to a serious adverse event report submitted to the Secretary in accordance with paragraph (1), that is received by the responsible person within 1 year of the initial report to the Secretary, no later than 15 business days after such information is received by such responsible person.

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