

(3) would not unduly burden interstate commerce.

(c) Scope

For purposes of subsection (a) of this section, a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this chapter for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

(d) No effect on product liability law

Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(e) State initiative

This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(June 25, 1938, ch. 675, §752, as added Pub. L. 105-115, title IV, §412(d), Nov. 21, 1997, 111 Stat. 2376.)

REFERENCES IN TEXT

The Poison Prevention Packaging Act of 1970, referred to in subsec. (a), is Pub. L. 91-601, Dec. 30, 1970, 84 Stat. 1670, as amended, which is classified principally to chapter 39A (§1471 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1471 of Title 15 and Tables.

The Fair Packaging and Labeling Act, referred to in subsec. (a), is Pub. L. 89-755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1451 of Title 15 and Tables.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

PART G—SAFETY REPORTS

§ 379v. Safety report disclaimers

With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this chapter (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or con-

tributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.

(June 25, 1938, ch. 675, §756, as added Pub. L. 105-115, title IV, §420, Nov. 21, 1997, 111 Stat. 2379.)

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

PART H—SERIOUS ADVERSE EVENT REPORTS

§ 379aa. Serious adverse event reporting for non-prescription drugs

(a) Definitions

In this section:

(1) Adverse event

The term “adverse event” means any health-related event associated with the use of a non-prescription 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).

(b) Reporting requirement

(1) In general

The manufacturer, packer, or distributor whose name (pursuant to section 352(b)(1) of this title) appears on the label of a non-prescription drug marketed in the United States (referred to in this section as the “responsible person”) shall submit to the Sec-