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 contributed 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 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).

(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 nonprescription drug marketed in the United States (referred to in this section as the ''responsible person'') shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

(2) Retailer

A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such drug that are reported to the retailer through the address or telephone number described in section 352(x) of this title.

(c) Submission of reports

(1) Timing of reports

The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 352(x) of this title.