

“(E) with respect to a requirement of a State or political subdivision described in paragraph (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(r) of such Act take effect.

“(2) EXCEPTION.—If a State or political subdivision submits a petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act for a requirement described in section 403A(a) of such Act within 18 months of the date of the enactment of this Act, paragraphs (3) through (5) of such section 403A(a) shall not apply with respect to such State or political subdivision requirement until—

“(A) 24 months after the date of the enactment of this Act, or

“(B) action on the petition, whichever occurs later.

“(3) REQUIREMENTS PERTAINING TO CERTAIN CLAIMS.—Notwithstanding subparagraphs (D) and (E) of paragraph (1) and except with respect to claims approved in accordance with section 202(b) of the Dietary Supplement Act of 1992 [Pub. L. 102-571, set out as a note under section 343 of this title], the requirements described in paragraphs (4) and (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(4) and (5)) that pertain to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not take effect until the date final regulations take effect to implement subsection (q) or (r), as appropriate, of section 403 of such Act with respect to such dietary supplements.”

Pub. L. 101-535, §6(b), Nov. 8, 1990, 104 Stat. 2363, provided that:

“(1) For the purpose of implementing section 403A(a)(3) [21 U.S.C. 343-1(a)(3)], the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

“(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(b), (d), (f), (h), (i)(1), (k)], and

“(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

“(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act [Nov. 8, 1990].

“(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

“(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

“(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in effect any requirement which is not identical to the requirement of the section

which had its regulations revised in accordance with this subparagraph.

“(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

“(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

“(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C).”

CONSTRUCTION OF PUB. L. 101-535

Pub. L. 101-535, §6(c), Nov. 8, 1990, 104 Stat. 2364, provided that:

“(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535, see Short Title of 1990 Amendment note set out under section 301 of this title] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act [this section].

“(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

“(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.”

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

DELAYED APPLICABILITY OF CERTAIN PROVISIONS

Pub. L. 102-408, title III, §310, Oct. 13, 1992, 106 Stat. 2090, provided that: “Notwithstanding any other provision of law, section 403A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(1)) shall not apply with respect to any requirement of any State or political subdivision regarding maple syrup until September 1, 1994.”

§ 343-2. Dietary supplement labeling exemptions

(a) In general

A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) Application

Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

(c) Burden of proof

In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

(June 25, 1938, ch. 675, §403B, as added Pub. L. 103-417, §5, Oct. 25, 1994, 108 Stat. 4328.)

§ 343-3. Disclosure

(a) No provision of section 321(n), 343(a), or 348 of this title shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 343(i)(2) of this title.

(b) In this section, the term “radiation disclosure statement” means a written statement that discloses that a food has been intentionally subject to radiation.

(June 25, 1938, ch. 675, §403C, as added Pub. L. 105-115, title III, §306, Nov. 21, 1997, 111 Stat. 2353.)

Statutory Notes and Related Subsidiaries

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.

§ 343a. Repealed. Pub. L. 106-554, § 1(a)(1) [title V, § 517], Dec. 21, 2000, 114 Stat. 2763, 2763A-73

Section, Pub. L. 95-203, §4(c), (d), Nov. 23, 1977, 91 Stat. 1453, 1454, related to distribution of information on health risks of saccharin.

§ 344. Emergency permit control

(a) Conditions on manufacturing, processing, etc., as health measure

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the

issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) Violation of permit; suspension and reinstatement

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Inspection of permit-holding establishments

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

(June 25, 1938, ch. 675, §404, 52 Stat. 1048.)

Statutory Notes and Related Subsidiaries

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

§ 345. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.

(June 25, 1938, ch. 675, §405, 52 Stat. 1049; Pub. L. 101-535, §5(a), Nov. 8, 1990, 104 Stat. 2362.)