lead and cadmium based enamel on glass and ceramic ware—

''(1) which has less than 60 millimeters of decorating area below the external rim, and

''(2) which is not, by design, representation, or custom of usage intended for use by children,

is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware. Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.''

MORATORIUM ON AUTHORITY OF SECRETARY WITH RESPECT TO SACCHARIN

Pub. L. 95–203, § 3, Nov. 23, 1977, 91 Stat. 1452, as amended by Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 96–273, June 17, 1980, 94 Stat. 536; Pub. L. 97–42, § 2, Aug. 14, 1981, 95 Stat. 946; Pub. L. 98–22, § 2, Apr. 22, 1983, 97 Stat. 173; Pub. L. 99–46, May 24, 1985, 99 Stat. 81; Pub. L. 100–71, title I, § 101, July 11, 1987, 101 Stat. 431; Pub. L. 102–142, title VI, Oct. 28, 1991, 105 Stat. 910; Pub. L. 104–180, title VI, § 602, Aug. 6, 1996, 110 Stat. 1594, provided that: ''During the period ending May 1, 2002, the Secretary—

''(1) may not amend or revoke the interim food additive regulation of the Food and Drug Administration of the Department of Health and Human Services applicable to saccharin and published on March 15, 1977 (section 180.37 of part 180, subchapter B, chapter 1, title 21, Code of Federal Regulations (42 Fed. Reg. 14638)), or

''(2) may, except as provided in section 4 [enacting section 343a of this title, amending sections 321 and 343 of this title, and enacting provisions set out as notes under section 343 of this title] and the amendments made by such section, not take any other action under the Federal Food, Drug, and Cosmetic Act [this chapter] to prohibit or restrict the sale or distribution of saccharin, any food permitted by such interim food additive regulation to contain saccharin, or any drug or cosmetic containing saccharin,

solely on the basis of the carcinogenic or other toxic effect of saccharin as determined by any study made available to the Secretary before the date of the enactment of this Act [Nov. 23, 1977] which involved human studies or animal testing, or both.''

[Definition of ''saccharin'' as used in section 3 of Pub. L. 95–203, set out above, to include calcium saccharin, sodium saccharin, and ammonium saccharin, see Pub. L. 95–203, § 2(d), Nov. 23, 1997, 91 Stat. 1452.]

§ 349. Bottled drinking water standards; publication in Federal Register

(a) Except as provided in subsection (b), whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 1412 of the Public Health Service Act [42 U.S.C. 300g–1], the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments.

(b)(1) Not later than 180 days before the effective date of a national primary drinking water regulation promulgated by the Administrator of the Environmental Protection Agency for a contaminant under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the Secretary shall promulgate a standard of quality regulation under this subsection for that contaminant in bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems (as defined under section 1401(4) of such Act (42 U.S.C. 300f(4))) but not in water used for bottled drinking water. The effective date for any such standard of quality regulation shall be the same as the effective date for such national primary drinking water regulation, except for any standard of quality of regulation promulgated by the Secretary before August 6, 1996, for which (as of August 6, 1996) an effective date had not been established. In the case of a standard of quality regulation to which such exception applies, the Secretary shall promulgate monitoring requirements for the contaminants covered by the regulation not later than 2 years after August 6, 1996.

(2) A regulation issued by the Secretary as provided in this subsection shall include any monitoring requirements that the Secretary determines appropriate for bottled water.

(3) A regulation issued by the Secretary as provided in this subsection shall require the following:

(A) In the case of contaminants for which a maximum contaminant level is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the regulation under this subsection shall establish a maximum contaminant level for the contaminant in bottled water which is no less stringent than the maximum contaminant level provided in the national primary drinking water regulation.

(B) In the case of contaminants for which a treatment technique is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the regulation under this subsection shall require that bottled water be subject to requirements no less protective of the public health than those applicable to water provided by public water systems using the treatment technique required by the national primary drinking water regulation.

(4)(A) If the Secretary does not promulgate a regulation under this subsection within the period described in paragraph (1), the national primary drinking water regulation referred to in paragraph (1) shall be considered, as of the date on which the Secretary is required to establish a regulation under paragraph (1), as the regulation applicable under this subsection to bottled water.

(B) In the case of a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation, the Secretary shall, not later than the applicable date referred to in such subparagraph, publish in the Federal Register a notice—

(i) specifying the contents of such regulation, including monitoring requirements; and

(ii) providing that for purposes of this paragraph the effective date for such regulation is the same as the effective date for the regulation for purposes of the Safe Drinking Water Act [42 U.S.C. 300f et seq.] (or, if the exception

under paragraph (1) applies to the regulation, that the effective date for the regulation is not later than 2 years and 180 days after August 6, 1996).

(June 25, 1938, ch. 675, §410, as added Pub. L. 93–523, §4, Dec. 16, 1974, 88 Stat. 1694; amended Pub. L. 104–182, title III, §305, Aug. 6, 1996, 110 Stat. 1684.)

Editorial Notes

REFERENCES IN TEXT

The Safe Drinking Water Act, referred to in subsec. (b)(4)(B)(ii), is title XIV of act July 1, 1944, as added Dec. 16, 1974, Pub. L. 93–523, §2(a), 88 Stat. 1660, as amended, which is classified generally to subchapter XII (§300f et seq.) of chapter 6A of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

1996—Pub. L. 104–182 substituted ''(a) Except as provided in subsection (b), whenever'' for ''Whenever'' and added subsec. (b).

Statutory Notes and Related Subsidiaries

BOTTLED WATER STUDY

Pub. L. 104–182, title I, §114(b), Aug. 6, 1996, 110 Stat. 1641, provided that not later than 18 months after Aug. 6, 1996, the Administrator of the Food and Drug Administration would publish for public notice and comment a draft study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water, and publish a final study not later than 30 months after Aug. 6, 1996.

§350. Vitamins and minerals

(a) Authority and limitations of Secretary; applicability

(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321(n), 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 321(n), 341, or 343 of this title, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph,[1] the term ''children'' means individuals who are under the age of twelve years.

[1] So in original. Probably should be ''paragraph''.

(b) Labeling and advertising requirements for foods

(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 321(ff) of this title (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(c) Definitions

(1) For purposes of this section, the term ''food to which this section applies'' means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term ''special dietary use'' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(June 25, 1938, ch. 675, §411, as added Pub. L. 94–278, title V, §501(a), Apr. 22, 1976, 90 Stat. 410; amended Pub. L. 103–417, §§3(c), 7(d), Oct. 25, 1994, 108 Stat. 4328, 4331.)