

Subsec. (c)(1)(B)(ii). Pub. L. 103-417, §3(c)(2), struck out “does not simulate and” after “in such a form.”

EFFECTIVE DATE OF 1994 AMENDMENT

For provision that dietary supplements may be labeled after Oct. 25, 1994, in accordance with amendments made by section 7(d) of Pub. L. 103-417, and shall be so labeled after Dec. 31, 1996, see section 7(e) of Pub. L. 103-417, set out as a note under section 343 of this title.

AMENDMENT OF INCONSISTENT REGULATIONS BY SECRETARY

Section 501(b) of Pub. L. 94-278, as amended by Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, provided that: “The Secretary of Health and Human Services shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act [this chapter] which is inconsistent with section 411 of such Act [section 350 of this title] (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 343 of this title.

§ 350a. Infant formulas

(a) Adulteration

An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

- (1) such infant formula does not provide nutrients as required by subsection (i) of this section,
- (2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1) of this section, or
- (3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2) of this section.

(b) Requirements for quality factors, good manufacturing practices, and retention of records

(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i) of this section.

(2)(A) The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with this subsection and subsection (i) of this section and is manufactured in a manner designed to prevent adulteration of the infant formula.

(B) The good manufacturing practices and quality control procedures prescribed by the Secretary under subparagraph (A) shall include requirements for—

- (i) the testing, in accordance with paragraph (3) and by the manufacturer of an infant formula or an agent of such manufacturer, of each batch of infant formula for each nutrient required by subsection (i) of this section before the distribution of such batch,
- (ii) regularly scheduled testing, by the manufacturer of an infant formula or an agent of

such manufacturer, of samples of infant formulas during the shelf life of such formulas to ensure that such formulas are in compliance with this section,

(iii) in-process controls including, where necessary, testing required by good manufacturing practices designed to prevent adulteration of each batch of infant formula, and

(iv) the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under subparagraph (A).

In prescribing requirements for audits under clause (iv), the Secretary shall provide that such audits be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.

(3)(A) At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E to ensure that such infant formula is in compliance with the requirements of this subsection and subsection (i) of this section relating to such vitamins.

(B) Each nutrient premix used in the manufacture of an infant formula shall be tested for each relied upon nutrient required by subsection (i) of this section which is contained in such premix to ensure that such premix is in compliance with its specifications or certifications by a premix supplier.

(C) During the manufacturing process or at the final product stage and before distribution of an infant formula, an infant formula shall be tested for all nutrients required to be included in such formula by subsection (i) of this section for which testing has not been conducted pursuant to subparagraph (A) or (B). Testing under this subparagraph shall be conducted to—

- (i) ensure that each batch of such infant formula is in compliance with the requirements of subsection (i) of this section relating to such nutrients, and
- (ii) confirm that nutrients contained in any nutrient premix used in such infant formula are present in each batch of such infant formula in the proper concentration.

(D) If the Secretary adds a nutrient to the list of nutrients in the table in subsection (i) of this section, the Secretary shall by regulation require that the manufacturer of an infant formula test each batch of such formula for such new nutrient in accordance with subparagraph (A), (B), or (C).

(E) For purposes of this paragraph, the term “final product stage” means the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and is not subject to further degradation.

(4)(A) The Secretary shall by regulation establish requirements respecting the retention of records. Such requirements shall provide for—

- (i) the retention of all records necessary to demonstrate compliance with the good manufacturing practices and quality control procedures prescribed by the Secretary under para-

graph (2), including records containing the results of all testing required under paragraph (2)(B),

(ii) the retention of all certifications or guarantees of analysis by premix suppliers,

(iii) the retention by a premix supplier of all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis,

(iv) the retention of—

(I) all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder and in finished infant formula, and

(II) all records pertaining to food packaging materials which show that such materials do not cause an infant formula to be adulterated within the meaning of section 342(a)(2)(C) of this title,

(v) the retention of all records of the results of regularly scheduled audits conducted pursuant to the requirements prescribed by the Secretary under paragraph (2)(B)(iv), and

(vi) the retention of all complaints and the maintenance of files with respect to, and the review of, complaints concerning infant formulas which may reveal the possible existence of a hazard to health.

(B)(i) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Except as provided in clause (ii), such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

(ii) A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(iv) are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of such audits.

(c) Registration of persons distributing new infant formula

(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, and

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c)(1) of this section.

(2) For purposes of paragraph (1), the term “new infant formula” includes—

(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and

(B) an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer.

For purposes of this paragraph, the term “major change” has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder.

(d) Submission of information about new infant formula required

(1) A person shall, with respect to any infant formula subject to subsection (c) of this section, make a submission to the Secretary which shall include—

(A) the quantitative formulation of the infant formula,

(B) a description of any reformulation of the formula or change in processing of the infant formula,

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i) of this section, as demonstrated by the testing required under subsection (b)(3) of this section, and

(D) assurances that the processing of the infant formula complies with subsection (b)(2) of this section.

(2) After the first production of an infant formula subject to subsection (c) of this section, and before the introduction into interstate commerce of such formula, the manufacturer of such formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification which summarizes test results and records demonstrating that such formula complies with the requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i) of this section.

(3) If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a) of this section, the manufacturer shall, before the first processing of such formula, make the submission to the Secretary required by paragraph (1).

(e) Additional notice requirements for manufacturer

(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not provide the nutrients required by subsection (i) of this section, or

(B) may be otherwise adulterated or misbranded,

the manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(2) For purposes of paragraph (1), the term “knowledge” as applied to a manufacturer means (A) the actual knowledge that the manu-

facturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(f) Procedures applicable to recalls by manufacturer; regulatory oversight

(1) If a recall of infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—

(A) the Secretary shall, not later than the 15th day after the beginning of such recall and at least once every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2), and

(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) The Secretary shall by regulation require each manufacturer of an infant formula who begins a recall of such formula because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase of such formula a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.

(g) Recordkeeping requirements for manufacturer; regulatory oversight and enforcement

(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1), the Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting the retention of such records under such paragraph. Such regulations shall take effect on such date as the Secretary prescribes but not sooner than the 180th day after the date such regulations are promulgated. Such regulations shall apply only with respect to distributions of infant formulas made after such effective date.

(h) Exemptions; regulatory oversight

(1) Any infant formula which is represented and labeled for use by an infant—

(A) who has an inborn error of metabolism or a low birth weight, or

(B) who otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a), (b), and (c) of this section. The manufacturer

of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(1) of this section only with respect to adulteration or misbranding described in subsection (e)(1)(B) of this section and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c) of this section. An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed under this paragraph.

(i) Nutrient requirements

(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under paragraph (2), as so revised.

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection, and

(B) revise the required level for any nutrient required by the table.

NUTRIENTS

Nutrient	Minimum ^a	Maximum ^a
Protein (gm)	1.8 ^b	4.5.
Fat:		
gm	3.3	6.0.
percent cal	30.0	54.0.
Essential fatty acids (linoleate):		
percent cal	2.7	
mg	300.0	
Vitamins:		
A (IU)	250.0	(75 µg) ^c 750.0 (225 µg). ^c
D (IU)	40.0	100.0.
K (µg)	4.0	
E (IU)	0.7	(with 0.7 IU/gm linoleic acid).
C (ascorbic acid) (mg).	8.0	
B ₁ (thiamine) (µg)	40.0	
B ₂ (riboflavin) (µg)	60.0	
B ₆ (pyridoxine) (µg)	35.0	(with 15 µg/gm of protein in formula).
B ₁₂ (µg)	0.15	
Niacin (µg)	250.0	
Folic acid (µg)	4.0	
Pantothenic acid (µg).	300.0	
Biotin (µg)	1.5 ^d	
Choline (mg)	7.0 ^d	
Inositol (mg)	4.0 ^d	
Minerals:		
Calcium (mg)	50.0 ^e	
Phosphorus (mg) ...	25.0 ^e	
Magnesium (mg) ...	6.0	
Iron (mg)	0.15	
Iodine (µg)	5.0	
Zinc (mg)	0.5	
Copper (µg)	60.0	
Manganese (µg)	5.0	
Sodium (mg)	20.0	60.0.

NUTRIENTS—Continued

Nutrient	Minimum ^a	Maximum ^a
Potassium (mg)	80.0	200.0.
Chloride (mg)	55.0	150.0.

^a Stated per 100 kilocalories.^b The source of protein shall be at least nutritionally equivalent to casein.^c Retinol equivalents.^d Required to be included in this amount only in formulas which are not milk-based.^e Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

(June 25, 1938, ch. 675, §412, as added Pub. L. 96-359, §2, Sept. 26, 1980, 94 Stat. 1190; amended Pub. L. 99-570, title IV, §4014(a), (b)(1), Oct. 27, 1986, 100 Stat. 3207-116, 3207-120; Pub. L. 103-80, §3(l), Aug. 13, 1993, 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (h)(1). Pub. L. 103-80 substituted “(e)(1)(B) of this section” for “(c)(1)(B) of this section,” in concluding provisions.

1986—Subsecs. (a) to (d). Pub. L. 99-570, §4014(a)(7), added subsecs. (a) to (d) and struck out former subsecs. (a) relating to adulteration and regulatory oversight, (b) relating to notice to the Secretary by a manufacturer and requirements and scope of that notice, (c) relating to additional notice requirements for the manufacturer, and (d) relating to procedures applicable to recalls by a manufacturer.

Subsecs. (e), (f). Pub. L. 99-570, §4014(a)(1), (7), added subsecs. (e) and (f) and redesignated former subsecs. (e) and (f) as (g) and (h), respectively.

Subsec. (g). Pub. L. 99-570, §4014(a)(1), (2), redesignated subsec. (e) as (g) and substituted “Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula” for “No manufacturer shall be required under this subsection to retain any record respecting the distribution of an infant formula for a period of longer than 2 years from the date the record was made”. Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 99-570, §4014(a)(1), redesignated subsec. (f) as (h).

Subsec. (h)(1). Pub. L. 99-570, §4014(a)(3), (4), substituted “(a), (b), and (c)” for “(a) and (b)” and “(e)(1)” for “(c)(1)”.

Pub. L. 99-570, §4014(a)(5), which directed that “(d)(1)(B)” be substituted for “(e)(1)(B)” in second sentence could not be executed because “(e)(1)(B)” did not appear. See 1993 Amendment note above.

Subsec. (h)(2). Pub. L. 99-570, §4014(a)(6), substituted “(a), (b), and (c)” for “(a) and (b)”.

Subsec. (i). Pub. L. 99-570, §4014(a)(1), (b)(1), redesignated subsec. (g) as (i), designated existing provisions as par. (1), substituted “paragraph (2)” for “subsection (a)(2) of this section”, substituted a period for the colon after “as so revised”, and added par. (2).

EFFECTIVE DATE OF 1980 AMENDMENT

Section 6 of Pub. L. 96-359 provided that: “Section 412 of the Federal Food, Drug, and Cosmetic Act (added by section 2) [this section] shall apply with respect to infant formulas manufactured on or after the 90th day after the date of the enactment of this Act [Sept. 26, 1980].”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 343, 374 of this title.

§ 350b. New dietary ingredients

(a) In general

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) Petition

Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, the decision of the Secretary shall be considered final agency action.

(c) “New dietary ingredient” defined

For purposes of this section, the term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

(June 25, 1938, ch. 675, §413, as added Pub. L. 103-417, §8, Oct. 25, 1994, 108 Stat. 4331.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or