

Public Law 96-359
96th Congress

An Act

Sept. 26, 1980

[H.R. 6940]

To amend the Federal Food, Drug, and Cosmetic Act to strengthen the authority under that Act to assure the safety and nutrition of infant formulas, and for other purposes.

Infant Formula
Act of 1980.
21 USC 301 note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Infant Formula Act of 1980".

SEC. 2. Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 411 the following new section:

"REQUIREMENTS FOR INFANT FORMULAS

Adulterated
formulas.
21 USC 350a.

"SEC. 412. (a)(1) An infant formula shall be deemed to be adulterated if—

"(A) such infant formula does not provide nutrients as required by subsection (g);

"(B) such infant formula does not meet the quality factor requirements prescribed by the Secretary under this section; or

"(C) the processing of such infant formula is not in compliance with the quality control requirements prescribed by the Secretary under this section.

"(2) The Secretary may by regulation—

"(A) revise the list of nutrients in the table in subsection (g);

"(B) revise the required level for any nutrient required by subsection (g);

"(C) establish requirements for quality factors for such nutrients; and

"(D) establish such quality control procedures as the Secretary determines necessary to assure that an infant formula provides nutrients in accordance with this section and establish requirements respecting the retention of records of procedures required under this clause (including maintaining necessary nutrient testing records).

Quality control
procedures.

Quality control procedures prescribed by the Secretary shall include the periodic testing of infant formulas to determine whether they are in compliance with this section.

Testing.

"(b)(1) On the 90th day after the date of the enactment of this section, and on each 90th day thereafter, a manufacturer of infant formula shall notify the Secretary that each infant formula manufactured by such manufacturer provides the nutrients required under subsection (g). Such notification requirement shall expire upon the effective date of regulations relating to quality control procedures prescribed by the Secretary under subsection (a)(2)(D).

"(2) Not later than the 90th day before the first processing of any infant formula for commercial or charitable distribution for human consumption, the manufacturer shall notify the Secretary whether—

"(A) such infant formula provides nutrients in accordance with subsection (g) and meets the quality factor requirements prescribed by the Secretary; and

"(B) the processing of such infant formula meets the quality control procedure requirements prescribed by the Secretary.

Notification to
Secretary.

"(3) Before the first processing of any infant formula for commercial or charitable distribution for human consumption—

- "(A) after a change in its formulation, or
- "(B) after a change in its processing,

which the manufacturer reasonably determines may affect whether the formula is adulterated as determined under subsection (a)(1), the manufacturer shall notify the Secretary of such changes and that the formula provides nutrients in accordance with subsection (g) and meets the quality factor requirements prescribed by the Secretary and that the processing of such infant formula is in compliance with the quality control procedures prescribed by the Secretary.

"(c)(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 (g);
or

- "(B)(i) may be otherwise adulterated or misbranded, and
(ii) if so adulterated or misbranded presents a risk to human health,

the manufacturer shall promptly notify the Secretary of such non-compliance or risk to health.

"(2) For purposes of paragraph (1), the term 'knowledge' as applied to a manufacturer means (A) the actual knowledge that the manufacturer 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.

"Knowledge."

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

Recall.

"(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

Review.

"(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.

Report to
Secretary.

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

Regulations.

"(e)(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. 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.

Records.

"(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.

Exemptions.

"(f)(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) and (b). 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 (c)(1) only with respect to adulteration or misbranding described in subsection (c)(1)(B), 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) and (b). 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.

Nutrient contents.

"(g) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under subsection (a)(2), as so revised:

"NUTRIENTS

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

* 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.

SEC. 3. Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

“(aa) The term ‘infant formula’ means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.”

“Infant formula.”

SEC. 4. Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended—

(1) in the first sentence, by inserting “(1)” before “For purposes” and by redesignating clauses (1) and (2) as clauses (A) and (B), respectively;

(2) in the third sentence, by inserting “or by paragraph (3)” after “preceding sentence”;

(3) in the sixth sentence, (A) by striking out “The provisions of the second sentence of this subsection” and inserting in lieu thereof the following:

“(2) The provisions of the second sentence of paragraph (1), and (B) by redesignating paragraphs (1) through (4) as subparagraphs (A) through (D), respectively; and

(4) by adding at the end the following:

“(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

“(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

“(B) required to be maintained under section 412.”

Ante, p. 1190.

SEC. 5. (a) Section 301 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new paragraph:

“(s) The failure to provide the notice required by section 412(b) or 412(c), the failure to make the reports required by section 412(d)(1)(B), or the failure to meet the requirements prescribed under section 412(d)(2).”

21 USC 331.

(b) Section 301(e) of such Act is amended (1) by striking out “section 703” and inserting in lieu thereof “section 412 or 703”, and (2) by striking out “section 505” and inserting in lieu thereof “section 412, 505”.

(c) Section 301(j) of such Act is amended by inserting “412,” before “505”.

SEC. 6. Section 412 of the Federal Food, Drug, and Cosmetic Act (added by section 2) shall apply with respect to infant formulas manufactured on or after the 90th day after the date of the enactment of this Act.

Effective date.
21 USC 350a
note.

SEC. 7. (a) The Secretary of Health and Human Services shall conduct a study to determine the long-term effect on infants of hypochloremic metabolic alkalosis resulting from infant formulas deficient in chloride. The Secretary shall report the results of such study to the Congress.

Health study.

(b) The Secretary of Health and Human Services shall conduct a review of existing Federal requirements for the labeling of infant formula to determine the effect of such requirements on infant nutrition and proper use of infant formula. Not later than the 180th day after the date of the enactment of this Act, the Secretary shall

Report to
Congress.

Federal labeling
requirements,
review.

Submittal to
congressional
committees.

submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives containing the results of the review and including recommendations for any legislative or administrative action with respect to the labeling of infant formula as the Secretary determines appropriate.

Export issues, review.

Ante, p. 1190.
Submittal to congressional committees.

Controlled substance with highest abuse rate.

21 USC 830, 841,
842, 843.

Penalties.

(c) The Secretary of Health and Human Services shall conduct a review of issues concerning the export of infant formula that, if marketed in the United States, would be in violation of section 412 of the Federal Food, Drug, and Cosmetic Act. Not later than the 180th day after the date of enactment of this Act, the Secretary shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives, containing the results of the review and including recommendations regarding appropriate legislative or administrative action to improve current export policies, as the Secretary determines appropriate.

SEC. 8. (a) Section 503 of the Controlled Substances Act (21 U.S.C. 873) is amended by adding at the end the following new subsection:

“(c) The Attorney General shall annually (1) select the controlled substance (or controlled substances) contained in schedule II which, in the Attorney General's discretion, is determined to have the highest rate of abuse, and (2) prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States of each such controlled substance.”

(b) Section 203 of the Psychotropic Substances Act of 1978 (Public Law 95-633) is amended by striking out subsection (d).

(c) Section 401 of the Controlled Substances Act (21 U.S.C. 841) is amended—

(1) by striking out “except as provided in paragraphs (4) and (5) of this subsection” in the first sentence of subsection (b)(1)(B) and inserting in lieu thereof “except as provided in paragraphs (4), (5), and (6) of this subsection”; and

(2) by adding after paragraph (5) of subsection (b) the following new paragraph:

“(6) In the case of a violation of subsection (a) involving a quantity of marihuana exceeding 1,000 pounds, such person shall be sentenced to a term of imprisonment of not more than 15 years, and in addition, may be fined not more than \$125,000. If any person commits such a violation after one or more prior convictions of such person for an offense punishable under paragraph (1) of this paragraph, or for a

felony under any other provision of this title, title III, or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, and in addition, may be fined not more than \$250,000.".

Approved September 26, 1980.

LEGISLATIVE HISTORY:

HOUSE REPORT No. 96-936 (Comm. on Interstate and Foreign Commerce).
SENATE REPORT No. 96-916 accompanying S. 2490 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 126 (1980):

May 20, considered and passed House.
Sept. 8, considered and passed Senate, amended, in lieu of S. 2490.
Sept. 9, House concurred in Senate amendment.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 16, No. 39:
Sept. 26, Presidential remarks and statement.