

Union Calendar No. 177

105TH CONGRESS
1ST Session

H. R. 2469

[Report No. 105-306]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes.

OCTOBER 6, 1997

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food ingredients, nutrient content claims, and health claims, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 11, 1997

Mr. WHITFIELD (for himself, Mr. TOWNS, Mr. KLUG, Mr. HALL of Texas, Mr. GREENWOOD, Mr. MANTON, Mr. BURR of North Carolina, Ms. MCCARTHY of Missouri, Mr. BARTON of Texas, Mr. COBURN, Mr. UPTON, Mr. DEAL of Georgia, Mr. BILIRAKIS, Mr. ENGEL, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 6, 1997

Additional sponsors: Mr. GREEN, Mr. STRICKLAND, Mr. HASTERT, Mr. SAWYER, Mr. CANNON, Mr. BLILEY, and Mr. McHALE

OCTOBER 6, 1997

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on September 11, 1997]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regula-

tion of food ingredients, nutrient content claims, and health claims, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 **SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CON-**
 4 **TENTS.**

5 (a) *SHORT TITLE.*—*This Act may be cited as the*
 6 *“Food and Nutrition Information Reform Act of 1997”.*

7 (b) *REFERENCE.*—*Unless otherwise stated, whenever*
 8 *in this Act an amendment or repeal is expressed in terms*
 9 *of an amendment to, or repeal of, a section or other provi-*
 10 *sion, the reference shall be considered to be made to a section*
 11 *or other provision of the Federal Food, Drug, and Cosmetic*
 12 *Act (21 U.S.C. 321 et seq.).*

13 (c) *TABLE OF CONTENTS.*—*The table of contents is as*
 14 *follows:*

Sec. 1. Short title; reference; table of contents.

TITLE I—IMPROVING THE REGULATION AND LABELING OF FOOD

Sec. 101. Flexibility for regulations regarding claims.

Sec. 102. Petitions for claims.

Sec. 103. Health claims for food products.

Sec. 104. Nutrient content claims.

Sec. 105. Referral statements.

Sec. 106. Disclosure of irradiation.

Sec. 107. Irradiation petition.

Sec. 108. Glass and ceramic ware.

Sec. 109. Food contact substances.

Sec. 110. Margarine.

TITLE II—EFFECTIVE DATE

Sec. 201. Effective date.

1 ***TITLE I—IMPROVING THE REGU-***
 2 ***LATION AND LABELING OF***
 3 ***FOOD***

4 ***SEC. 101. FLEXIBILITY FOR REGULATIONS REGARDING***
 5 ***CLAIMS.***

6 *Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended by*
 7 *adding at the end the following:*

8 *“(D) Subject to the time period in the last sentence*
 9 *of clause (A)(i), proposed regulations under this paragraph*
 10 *may be made effective upon publication at the discretion*
 11 *of the Secretary, notwithstanding the provisions of section*
 12 *553 of title 5, United States Code, pending consideration*
 13 *of public comment and publication of a final regulation.*
 14 *Such regulations shall be deemed final agency action for*
 15 *purposes of judicial review.”.*

16 ***SEC. 102. PETITIONS FOR CLAIMS.***

17 *Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is*
 18 *amended—*

19 *(1) by adding after the second sentence the fol-*
 20 *lowing: “If the Secretary does not act within such 100*
 21 *days, the petition shall be deemed to be denied unless*
 22 *an extension is mutually agreed upon by the Sec-*
 23 *retary and the petitioner.”;*

24 *(2) in the fourth sentence (as amended by para-*
 25 *graph (1)) by inserting immediately before the comma*

1 the following: “or the petition is deemed to be de-
2 nied”; and

3 (3) by adding at the end the following: “If the
4 Secretary does not act within such 90 days, the peti-
5 tion shall be deemed to be denied unless an extension
6 is mutually agreed upon by the Secretary and the pe-
7 titioner. If the Secretary issues a proposed regulation,
8 the rulemaking shall be completed within 540 days of
9 the date the petition is received by the Secretary. If
10 the Secretary does not issue such a proposed regula-
11 tion within such 540 days, the Secretary shall provide
12 the Committee on Commerce of the House of Rep-
13 resentatives and the Committee on Labor and Human
14 Resources of the Senate the reasons action on the pro-
15 posed regulation did not occur within such 540
16 days.”.

17 **SEC. 103. HEALTH CLAIMS FOR FOOD PRODUCTS.**

18 Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by
19 adding at the end thereof the following:

20 “(C) Notwithstanding the provisions of clauses (A)(i)
21 and (B), a claim of the type described in subparagraph
22 (1)(B) which is not authorized by the Secretary in a regula-
23 tion promulgated in accordance with clause (B) shall be
24 authorized and may be made with respect to a food if—

1 “(i) a scientific body of the United States Gov-
2 ernment with official responsibility for public health
3 protection or research directly relating to human nu-
4 trition (such as the National Institutes of Health or
5 the Centers for Disease Control and Prevention) or
6 the National Academy of Sciences or any of its sub-
7 divisions has published an authoritative statement,
8 which is currently in effect, about the relationship be-
9 tween a nutrient and a disease or health-related con-
10 dition to which the claim refers;

11 “(ii) a person has submitted to the Secretary, at
12 least 150 days (during which the Secretary may issue
13 a regulation described in subparagraph (4)(D) and
14 may notify any person who is making a claim as au-
15 thorized by clause (C) that such person has not sub-
16 mitted all the information required by such clause)
17 before the first introduction into interstate commerce
18 of the food with a label containing the claim, (I) a
19 notice of the claim, which shall include the exact
20 words used in the claim and shall include a concise
21 description of the basis upon which such person relied
22 for determining that the requirements of subclause (i)
23 have been satisfied, (II) a copy of the statement re-
24 ferred to in subclause (i) upon which such person re-
25 lied in making the claim, and (III) a balanced rep-

1 *resentation of the scientific literature, including a*
2 *bibliography of such literature, relating to the rela-*
3 *ationship between a nutrient and a disease or health-*
4 *related condition to which the claim refers;*

5 *“(iii) the claim and the food for which the claim*
6 *is made are in compliance with clause (A)(ii) and are*
7 *otherwise in compliance with paragraph (a) and sec-*
8 *tion 201(n); and*

9 *“(iv) the claim is stated in a manner so that the*
10 *claim is an accurate representation of the authori-*
11 *tative statement referred to in subclause (i) and so*
12 *that the claim enables the public to comprehend the*
13 *information provided in the claim and to understand*
14 *the relative significance of such information in the*
15 *context of a total daily diet.*

16 *For purposes of this clause, a statement shall be regarded*
17 *as an authoritative statement of a scientific body described*
18 *in subclause (i) only if the statement is published by the*
19 *scientific body and shall not include a statement of an em-*
20 *ployee of the scientific body made in the individual capac-*
21 *ity of the employee.*

22 *“(D) A claim submitted under the requirements of*
23 *clause (C) may be made until—*

1 “(i) such time as the Secretary issues a regula-
 2 tion (including a regulation described in subpara-
 3 graph (4)(D)) under the standard in clause (B)(i)—

4 “(I) prohibiting or modifying the claim and
 5 the regulation has become effective, or

6 “(II) finding that the requirements of clause
 7 (C) have not been met, including finding that the
 8 petitioner has not submitted all the information
 9 required by such clause; or

10 “(ii) a district court of the United States in an
 11 enforcement proceeding under chapter III has deter-
 12 mined that the requirements of clause (C) have not
 13 been met.”.

14 **SEC. 104. NUTRIENT CONTENT CLAIMS.**

15 Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by
 16 adding at the end the following:

17 “(G) A claim of the type described in subparagraph
 18 (1)(A) for a nutrient, for which the Secretary has not pro-
 19 mulgated a regulation under clause (A)(i), shall be author-
 20 ized and may be made with respect to a food if—

21 “(i) a scientific body of the United States Gov-
 22 ernment with official responsibility for public health
 23 protection or research directly relating to human nu-
 24 trition (such as the National Institutes of Health or
 25 the Centers for Disease Control and Prevention) or

1 *the National Academy of Sciences or any of its sub-*
2 *divisions has published an authoritative statement,*
3 *which is currently in effect, which identifies the nu-*
4 *trient level to which the claim refers;*

5 “(ii) a person has submitted to the Secretary, at
6 *least 150 days (during which the Secretary may issue*
7 *a regulation described in subparagraph (4)(D) and*
8 *may notify any person who is making a claim as au-*
9 *thorized by clause (C) that such person has not sub-*
10 *mitted all the information required by such clause)*
11 *before the first introduction into interstate commerce*
12 *of the food with a label containing the claim, (I) a*
13 *notice of the claim, which shall include the exact*
14 *words used in the claim and shall include a concise*
15 *description of the basis upon which such person relied*
16 *for determining that the requirements of subclause (i)*
17 *have been satisfied, (II) a copy of the statement re-*
18 *ferred to in subclause (i) upon which such person re-*
19 *lied in making the claim, and (III) a balanced rep-*
20 *resentation of the scientific literature, including a*
21 *bibliography of such literature, relating to the nutri-*
22 *ent level to which the claim refers;*

23 “(iii) the claim and the food for which the claim
24 *is made are in compliance with clauses (A) and (B),*

1 and are otherwise in compliance with paragraph (a)
2 and section 201(n); and

3 “(iv) the claim is stated in a manner so that the
4 claim is an accurate representation of the authori-
5 tative statement referred to in subclause (i) and so
6 that the claim enables the public to comprehend the
7 information provided in the claim and to understand
8 the relative significance of such information in the
9 context of a total daily diet.

10 For purposes of this clause, a statement shall be regarded
11 as an authoritative statement of a scientific body described
12 in subclause (i) only if the statement is published by the
13 scientific body and shall not include a statement of an em-
14 ployee of the scientific body made in the individual capac-
15 ity of the employee.

16 “(H) A claim submitted under the requirements of
17 clause (G) may be made until—

18 “(i) such time as the Secretary issues a regula-
19 tion (including a regulation described in subpara-
20 graph (4)(D))—

21 “(I) prohibiting or modifying the claim and
22 the regulation has become effective, or

23 “(II) finding that the requirements of clause
24 (G) have not been met, including finding that

1 *the petitioner had not submitted all the informa-*
2 *tion required by such clause; or*

3 “(ii) a district court of the United States in an
4 enforcement proceeding under chapter III has deter-
5 mined that the requirements of clause (G) have not
6 been met.”.

7 **SEC. 105. REFERRAL STATEMENTS.**

8 Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is
9 amended to read as follows:

10 “(B) If a claim described in subparagraph (1)(A) is
11 made with respect to a nutrient in a food, and the Secretary
12 makes a determination that the food contains a nutrient
13 at a level that increases to persons in the general population
14 the risk of a disease or health-related condition that is diet
15 related, then the label or labeling of such food shall contain,
16 prominently and in immediate proximity to such claim,
17 the following statement: ‘See nutrition information for ____
18 content.’ The blank shall identify the nutrient associated
19 with the increased disease or health-related condition risk.
20 In making the determination described in this clause, the
21 Secretary shall take into account the significance of the food
22 in the total daily diet.”.

23 **SEC. 106. DISCLOSURE OF IRRADIATION.**

24 Chapter IV (21 U.S.C. 341 et seq.) is amended by in-
25 serting after section 403B the following:

1 “DISCLOSURE

2 “SEC. 403C. (a) No provision of section 201(n),
3 403(a), or 409 shall be construed to require on the label
4 or labeling of a food a separate radiation disclosure state-
5 ment that is more prominent than the declaration of ingre-
6 dients required by section 403(i)(2).

7 “(b) In this section, the term ‘radiation disclosure
8 statement’ means a written statement or symbol that dis-
9 closes that a food or a component of the food has been inten-
10 tionally subject to radiation.”.

11 **SEC. 107. IRRADIATION PETITION.**

12 Not later than 60 days following the date of the enact-
13 ment of this Act, the Secretary of Health and Human Serv-
14 ices shall—

15 (1) make a final determination on any petition
16 pending with the Food and Drug Administration that
17 would permit the irradiation of red meat under sec-
18 tion 409(b)(1) of the Federal Food, Drug, and Cos-
19 metic Act; or

20 (2) provide the Committee on Commerce of the
21 House of Representatives and the Committee on Labor
22 and Human Resources of the Senate an explanation
23 of the process followed by the Food and Drug Admin-
24 istration in reviewing the petition referred to in

1 *paragraph (1) and the reasons action on the petition*
 2 *was delayed.*

3 **SEC. 108. GLASS AND CERAMIC WARE.**

4 *(a) IN GENERAL.—The Secretary may not implement*
 5 *any requirement which would ban, as an unapproved food*
 6 *additive, lead and cadmium based paints in the lip and*
 7 *rim area of glass and ceramic ware before the expiration*
 8 *of one year after the date such requirement is published.*

9 *(b) LEAD AND CADMIUM BASED PAINT.—Lead and*
 10 *cadmium based paint may not be banned as an unapproved*
 11 *food additive if it is on glass and ceramic ware—*

12 *(1) which has less than 60 millimeters of deco-*
 13 *rating area below the external rim; and*

14 *(2) which is not, by design, representation, or*
 15 *custom of usage intended for use by children.*

16 **SEC. 109. FOOD CONTACT SUBSTANCES.**

17 *(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21*
 18 *U.S.C. 348(a)) is amended—*

19 *(1) in paragraph (1)—*

20 *(A) by striking “subsection (i)” and insert-*
 21 *ing “subsection (j)”;* and

22 *(B) by striking at the end “or”;*

23 *(2) by striking the period at the end of para-*
 24 *graph (2) and inserting “; or”;*

1 (3) by inserting after paragraph (2) the follow-
2 ing:

3 “(3) in the case of a food additive that is a food
4 contact substance, there is—

5 “(A) in effect for such substance a regula-
6 tion issued under this section prescribing the
7 conditions under which such substance may be
8 safely used and such substance and the use of
9 such substance are in conformity with such regu-
10 lation; or

11 “(B) a notification submitted under sub-
12 section (h) that is in effect.”; and

13 (4) in the flush matter following paragraph (3)
14 (as added by paragraph (3)), by inserting “or notifi-
15 cation” after “regulation” each place it appears.

16 (b) *NOTIFICATION FOR FOOD CONTACT SUB-*
17 *STANCES.*—Section 409 (21 U.S.C. 348), as amended by
18 subsection (a), is further amended—

19 (1) by redesignating subsections (h) and (i), as
20 subsections (i) and (j), respectively;

21 (2) by inserting after subsection (g) the follow-
22 ing:

23 “*Notification Relating to a Food Contact Substance*

24 “(h)(1) Subject to such regulations as may be promul-
25 gated under paragraph (3), a person manufacturing or sup-

1 *plying a food contact substance may, at least 120 days*
2 *prior to the introduction or delivery for introduction into*
3 *interstate commerce of the food contact substance, notify the*
4 *Secretary of the—*

5 “(A) *name of the person;*

6 “(B) *identity and intended use of the food con-*
7 *tact substance; and*

8 “(C) *determination of the person that the in-*
9 *tended use of such food contact substance is safe under*
10 *the standard described in subsection (c)(3)(A).*

11 *The notification shall contain the information that forms*
12 *the basis of the determination and all information required*
13 *to be submitted by regulations promulgated by the Sec-*
14 *retary.*

15 “(2)(A) *A notification submitted under paragraph (1)*
16 *shall become effective 120 days after the date of receipt by*
17 *the Secretary and the food contact substance may be intro-*
18 *duced or delivered for introduction into interstate com-*
19 *merce, unless, within the 120-day period, the Secretary—*

20 “(i) *makes a determination that, based on the*
21 *data and information before the Secretary, such use*
22 *of the food contact substance has not been shown to*
23 *be safe under the standard described in subsection*
24 *(c)(3)(A), or*

1 “(ii) makes a determination under paragraph
2 (3) with respect to the need for a petition under sub-
3 section (b) for such food contact substance,
4 and informs the person of such determination.

5 “(B) A determination by the Secretary under subpara-
6 graph (A)(i) shall constitute final agency action subject to
7 judicial review.

8 “(C) A notification under this subsection shall be effec-
9 tive only with respect to the person identified in the notifi-
10 cation.

11 “(3)(A) The notification process in this subsection
12 shall be utilized for authorizing the marketing of a food con-
13 tact substance except where the Secretary determines that
14 submission and review of a petition under subsection (b)
15 is necessary to provide adequate assurance of safety, or
16 where the Secretary and the person manufacturing or sup-
17 plying the food contact substance agree that such person
18 should submit a petition under subsection (b).

19 “(B) The Secretary may promulgate regulations to
20 identify the circumstances in which a petition shall be filed
21 under subsection (b) and shall consider criteria such as the
22 probable consumption of a food contact substance and po-
23 tential toxicity of the food contact substance in determining
24 the circumstances in which a petition shall be filed under
25 subsection (b) with respect to the food contact substance.

1 “(4) *The Secretary shall keep confidential any infor-*
 2 *mation provided in a notification under paragraph (1) for*
 3 *120 days after receipt by the Secretary of the notification.*
 4 *After the expiration of such 120 days, the information shall*
 5 *be available to any interested party except for any matter*
 6 *in the notification that is a trade secret or confidential com-*
 7 *mercial information.*

8 “(5) *In this section, the term ‘food contact substance’*
 9 *means any substance intended for use as a component of*
 10 *materials used in manufacturing, packing, packaging,*
 11 *transporting, or holding food if such use is not intended*
 12 *to have any technical effect in such food.”;*

13 *(3) in subsection (i), as so redesignated by para-*
 14 *graph (1), by adding at the end the following: “The*
 15 *Secretary shall by regulation prescribe the procedure*
 16 *by which the Secretary may deem a notification*
 17 *under subsection (h) to be no longer in effect.”; and*

18 *(4) in subsection (j), as so redesignated by para-*
 19 *graph (1), by striking “subsections (b) to (h)” and in-*
 20 *serting “subsections (b) to (i)”.*

21 (c) *EFFECTIVE DATE.*—*Notifications under section*
 22 *409(h) of the Federal Food, Drug, and Cosmetic Act, as*
 23 *added by subsection (b), may be submitted beginning 18*
 24 *months after the date of enactment of this Act.*

1 **SEC. 110. MARGARINE.**

2 (a) SECTION 301(m).—Paragraph (m) of section 301
3 (21 U.S.C. 331) is amended by striking “section 407(b) or
4 407(c)” and inserting “section 407”.

5 (b) SECTION 407.—Section 407 (21 U.S.C. 347) is
6 amended to read as follows:

7 “OLEOMARGARINE AND MARGARINE

8 “SEC. 407. No person shall sell, or offer for sale, oleo-
9 margarine or colored margarine unless the principal dis-
10 play panel of such oleomargarine or margarine bears as
11 one of its principal features the word ‘oleomargarine’ or
12 ‘margarine’ which is in—

13 “(1) bold type on such panel;

14 “(2) a size reasonably related to the most promi-
15 nent printed matter; and

16 “(3) lines generally parallel to the base on which
17 the package rests as it is designed to be displayed.”.

18 (c) ACT OF MARCH 16, 1950.—Sections 3(a) and 6 of
19 the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are re-
20 pealed.

21 **TITLE II—EFFECTIVE DATE**

22 **SEC. 201. EFFECTIVE DATE.**

23 The amendments made by this Act shall take effect on
24 the date of the enactment of this Act.

Amend the title so as to read: “A bill to amend the
Federal Food, Drug, and Cosmetic Act and other stat-

utes to provide for improvements in the regulation of food, nutrient content claims, and health claims, and for other purposes.”.