

103^D CONGRESS
1ST SESSION

H. R. 2900

To clarify and revise the small business exemption from the nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 5, 1993

Mr. DINGELL (for himself, Mr. WAXMAN, Mr. MOORHEAD, and Mr. BLILEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To clarify and revise the small business exemption from the nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act 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.**

4 This Act may be cited as the “Nutrition Labeling and
5 Education Act Amendments of 1993”.

6 **SEC. 2. SMALL BUSINESS EXEMPTION.**

7 (a) APPLICATION OF EXISTING EXEMPTION.—

8 (1) BEFORE MAY 8, 1995.—Before May 8, 1995,
9 the exemption provided by section 403(q)(5)(D) of

1 the Federal Food, Drug, and Cosmetic Act shall be
2 available in accordance with the regulations of the
3 Secretary of Health and Human Services published
4 at 21 C.F.R. 101.9(j)(1)(i)(1993).

5 (2) AFTER MAY 8, 1995.—After May 8, 1995,
6 the exemption provided by section 403(q)(5)(D) of
7 the Federal Food, Drug, and Cosmetic Act shall
8 only be available with respect to food when it is sold
9 to consumers.

10 (b) NEW EXEMPTION.—Section 403(q)(5) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 343(q)(5)) is amended by redesignating clauses (E) and
13 (F) as clauses (F) and (G), respectively, and by adding
14 after clause (D) the following:

15 “(E)(i) During the 12-month period for which an ex-
16 emption from subparagraphs (1) and (2) is claimed pursu-
17 ant to this subclause, the requirements of such subpara-
18 graphs shall not apply to any food product if—

19 “(I) the labeling for such product does not pro-
20 vide nutrition information or make a claim subject
21 to paragraph (r),

22 “(II) the person who claims for such product an
23 exemption from such subparagraphs employed fewer
24 than an average of 100 full-time equivalent employ-
25 ees,

1 “(III) such person provided the notice described
2 in subclause (iii), and

3 “(IV) in the case of a food product which was
4 sold in the 12-month period preceding the period for
5 which an exemption was claimed, fewer than
6 100,000 units of such product were sold in the Unit-
7 ed States during such preceding period, or in the
8 case of a food product which was not sold in the 12-
9 month period preceding the period for which such
10 exemption is claimed, fewer than 100,000 units of
11 such product are reasonably anticipated to be sold in
12 the United States during the period for which such
13 exemption is claimed.

14 “(ii) During the 12-month period after the applicable
15 date referred to in this sentence, the requirements of sub-
16 paragraphs (1) and (2) shall not apply to any food product
17 which was first introduced into interstate commerce before
18 May 8, 1994, if the labeling for such product does not
19 provide nutrition information or make a claim subject to
20 paragraph (r), if such person provided the notice described
21 in subclause (iii), and if—

22 “(I) during the 12-month period preceding May
23 8, 1994, the person who claims for such product an
24 exemption from such subparagraphs employed fewer
25 than an average of 300 full-time equivalent employ-

1 ees and fewer than 600,000 units of such product
2 were sold in the United States,

3 “(II) during the 12-month period preceding
4 May 8, 1995, the person who claims for such prod-
5 uct an exemption from such subparagraphs em-
6 ployed fewer than an average of 300 full-time equiv-
7 alent employees and fewer than 400,000 units of
8 such product were sold in the United States, or

9 “(III) during the 12-month period preceding
10 May 8, 1996, the person who claims for such prod-
11 uct an exemption from such subparagraphs em-
12 ployed fewer than an average of 200 full-time equiv-
13 alent employees and fewer than 200,000 units of
14 such product were sold in the United States.

15 “(iii) The notice referred to in subclauses (i) and (ii)
16 shall be given to the Secretary prior to the beginning of
17 the period during which the exemption under subclause
18 (i) or (ii) is to be in effect, shall state that the person
19 claiming such exemption for a food product has complied
20 with the applicable requirements of subclause (i) or (ii),
21 and shall—

22 “(I) state the average number of full-time
23 equivalent employees such person employed during
24 the 12 months preceding the date such person
25 claims such exemption,

1 “(II) state the approximate number of units the
2 person claiming the exemption sold in the United
3 States,

4 “(III) if the exemption is claimed for a food
5 product which was sold in the 12-month period pre-
6 ceding the period for which the exemption was
7 claimed, state the approximate number of units of
8 such product which were sold in the United States
9 during such preceding period, and, if the exemption
10 is claimed for a food product which was not sold in
11 such preceding period, state the number of units of
12 such product which such person reasonably antici-
13 pates will be sold in the United States during the
14 period for which the exemption was claimed, and

15 “(IV) contain such information as the Secretary
16 may require to verify the information required by
17 the preceding provisions of this subclause if the Sec-
18 retary has questioned the validity of such informa-
19 tion.

20 If a person is not an importer, has fewer than 10 full-
21 time equivalent employees, and sells fewer than 10,000
22 units of any food product in any year, such person is not
23 required to file a notice for such product under this
24 subclause for such year.

1 “(iv) In the case of a person who claimed an exemp-
2 tion under subclause (i) or (ii), if, during the period of
3 such exemption, the number of full-time equivalent em-
4 ployees of such person exceeds the number in such
5 subclause or if the number of food products sold in the
6 United States exceeds the number in such subclause, such
7 exemption shall extend to the expiration of 18 months
8 after the date the number of full-time equivalent employ-
9 ees or food products sold exceeded the applicable number.

10 “(v) For any food product first introduced into inter-
11 state commerce after May 8, 2002, the Secretary may by
12 regulation lower the employee or units of food products
13 requirement of subclause (i) if the Secretary determines
14 that the cost of compliance with such lower requirement
15 will not place an undue burden on persons subject to such
16 lower requirement.

17 “(vi) For purposes of subclauses (i), (ii), (iii), (iv),
18 and (v)—

19 “(I) the term ‘unit’ means the packaging or, if
20 there is no packaging, the form in which a food
21 product is offered for sale to consumers,

22 “(II) the term ‘food product’ means food in any
23 sized package which is manufactured by a single
24 manufacturer or which bears the same brand name,

1 which bears the same statement of identity, and
2 which has similar preparation methods, and

3 “(III) the term ‘person’ in the case of a cor-
4 poration includes all domestic and foreign affiliates
5 of the corporation.”.

6 **SEC. 3. TECHNICAL AMENDMENTS TO FEDERAL FOOD,**
7 **DRUG, AND COSMETIC ACT.**

8 (a) REFERENCE.—Whenever in this section an
9 amendment or repeal is expressed in terms of an amend-
10 ment to, or repeal of, a section or other provision, the ref-
11 erence shall be considered to be made to a section or other
12 provision of the Federal Food, Drug, and Cosmetic Act.

13 (b) SECTION 201.—Paragraphs (w), (x), (y), (z),
14 (aa), (bb), (cc), (dd), (ee), and (ff) of section 201 (21
15 U.S.C 321) are redesignated as paragraphs (v), (w), (x),
16 (y), (z), (aa), (bb), (cc), (dd), and (ee) respectively.

17 (c) SECTION 301.—Section 301 (21 U.S.C. 331) is
18 amended—

19 (1) in subsection (j), by striking out “721, or
20 708” and inserting in lieu thereof “708, or 721”;
21 and

22 (2) in subsection (s), by striking out “412(d)”
23 and inserting in lieu thereof “412(e)”.

24 (d) SECTION 302.—Section 302 (21 U.S.C. 332) is
25 amended

1 (1) in subsection (a), by striking out “, and
2 subject to” and all that follows through “381),”,
3 and

4 (2) in subsection (b), by striking out the second
5 sentence.

6 (e) SECTION 303.—Section 303 (21 U.S.C. 333) is
7 amended by redesignating the second subsection (e) and
8 subsection (f) as subsections (f) and (g), respectively.

9 (f) SECTION 304.—Section 304 (21 U.S.C. 334) is
10 amended—

11 (1) in subsection (a)(1), by striking out “: *Pro-*
12 *vided, however, That no*” and inserting in lieu there-
13 of a period and “No”, and

14 (2) in subsection (d)(1)—

15 (A) by striking out “: *Provided, That*
16 *after*” and inserting in lieu thereof a period and
17 “After”,

18 (B) by striking out “: *Provided, however,*
19 *That the*” and inserting in lieu thereof a period
20 and “The”,

21 (C) by striking out “: *And provided fur-*
22 *ther, That where*” and inserting in lieu thereof
23 a period and “Where”, and

1 (D) by striking out “the foregoing proviso”
2 and inserting in lieu thereof “the preceding sen-
3 tence”

4 (g) SECTION 307.—Section 307(b)(3)(A) (21 U.S.C.
5 337(b)(3)(A)) is amended by striking out “Act” and in-
6 serting in lieu thereof “section”.

7 (h) SECTION 401.—Section 401 (21 U.S.C. 341) is
8 amended by striking out “and/or reasonable standards of
9 fill of container: *Provided*, That no” and inserting in lieu
10 thereof “or reasonable standards of fill of container. No”.

11 (i) SECTION 402.—Section 402 (21 U.S.C. 342) is
12 amended—

13 (1) by striking out “; or” at the end of sub-
14 paragraphs (1) and (2) of paragraph (a) and insert-
15 ing in lieu thereof a period and by striking out “if
16 it” at the beginning of subparagraph (3) of such
17 paragraph and inserting in lieu thereof “If it”,

18 (2) in paragraph (d)(1), by striking out “: *Pro-*
19 *vided*, That this clause” and inserting in lieu thereof
20 “, except that this subparagraph”, and

21 (3) in paragraph (d)(3), by striking out “: *Pro-*
22 *vided*, That this clause” and inserting in lieu thereof
23 “, except that this subparagraph” and by striking
24 out “: *And provided further*, That the Secretary
25 may, for the purpose of avoiding or resolving uncer-

1 tainty as to the application of this clause” and in-
2 sserting in lieu thereof “, except that the Secretary
3 may, for the purpose of avoiding or resolving uncer-
4 tainty as to the application of this subparagraph”.

5 (j) SECTION 403.—Section 403 (21 U.S.C. 343) is
6 amended—

7 (1) in paragraph (e), by striking out “: *Pro-*
8 *vided, That*” and inserting in lieu thereof “, except
9 that”,

10 (2) in paragraph (i), by striking out “, other
11 than those sold as such” and inserting in lieu there-
12 of “unless sold as spices, flavorings, or such colors”
13 and by striking out “: *Provided, That, to the extent*”
14 and inserting in lieu thereof a period and “To the
15 extent”,

16 (3) in paragraph (k), by striking out “: *Pro-*
17 *vided, That*” and inserting in lieu thereof “, except
18 that”,

19 (4) in paragraph (l), by striking out “: *Pro-*
20 *vided, however, That*” and inserting in lieu thereof “,
21 except that”;

22 (5) in paragraph (r)(1)(B), by striking out
23 “5(D)” and inserting in lieu thereof “(5)(D)”; and

1 (6) in paragraph (r)(4)(B), by striking out
2 “subsection” and inserting in lieu thereof “para-
3 graph”.

4 (k) SECTION 408.—Section 408 (21 U.S.C. 346a) is
5 amended—

6 (1) in subsection (a)(1), by striking out “Sec-
7 retary of Health and Human Services” and inserting
8 in lieu thereof “Administrator of the Environmental
9 Protection Agency (hereinafter in this section re-
10 ferred to as the ‘Administrator’)”,

11 (2) in subsection (d)(5), by striking out “sec-
12 tion 7(c) of the Administrative Procedure Act (5
13 U.S.C., sec. 1006(c))” and inserting in lieu thereof
14 “section 556(c) of title 5, United States Code”,

15 (3) in subsection (l), by striking out “It the
16 event” and inserting in lieu thereof “In the event”,

17 (4) in subsection (n), by striking out “of the
18 Federal Food, Drug, and Cosmetic Act”,

19 (5) in subsection (o), by striking out “Secretary
20 of Health and Human Services” each place it occurs
21 and inserting in lieu thereof “Administrator”, and

22 (6) by striking out “Secretary” each place it oc-
23 curs except when followed by “of Agriculture” and
24 inserting in lieu thereof “Administrator”.

1 (l) SECTION 412.—Section 412(h) (21 U.S.C.
2 350a(h)) is amended by striking out “(c)(1)(B),” and in-
3 serting in lieu thereof “(e)(1)(B)”.

4 (m) SECTION 502.—Section 502 (21 U.S.C. 352) is
5 amended—

6 (1) in paragraph (e)(3), by striking out “: *Pro-*
7 *vided further, That*” and inserting in lieu thereof “,
8 except that”,

9 (2) in paragraph (f), by striking out “: *Pro-*
10 *vided, That*” and inserting in lieu thereof “, except
11 that”,

12 (3) in paragraph (g), by striking out “: *Pro-*
13 *vided, That the method*” and inserting in lieu there-
14 of a period and “The method” and by striking out
15 “: *Provided further, That,*” and inserting in lieu
16 thereof “, except that”, and

17 (4) in paragraph (n), by striking out “: *Pro-*
18 *vided, That*” and inserting in lieu thereof “, except
19 that”.

20 (n) SECTION 505.—Section 505 (21 U.S.C. 355) is
21 amended—

22 (1) in subsection (j)(6)(A)—

23 (A) by striking out “Secretary” in clause

24 (ii) and inserting in lieu thereof “Secretary”,

25 and

1 (B) by inserting a comma after “Sec-
2 retary” the first time it appears in clause (iii).

3 (2) in subsection (k)(1), by striking out “: *Pro-*
4 *vided, however,* That regulations” and inserting in
5 lieu thereof a period and “Regulations”.

6 (o) SECTION 506.—Section 506(a) (21 U.S.C.
7 356(a)) is amended by striking out “Federal Security Ad-
8 ministrator” and “Administrator” each place it appears
9 and inserting in lieu thereof “Secretary”.

10 (p) SECTION 507.—Section 507 (21 U.S.C. 357) is
11 amended—

12 (1) in subsection (a), by striking out “Federal
13 Security Administrator” and “Administrator” each
14 place it appears and inserting in lieu thereof “Sec-
15 retary”,

16 (2) in subsection (e)—

17 (A) by striking out “section 507” each
18 place it occurs and inserting in lieu thereof
19 “this section”,

20 (B) by striking out “or 507” and inserting
21 in lieu thereof “or this section”, and

22 (C) by striking out “: *Provided,* That, for
23 purposes” and inserting in lieu thereof a period
24 and “For purposes”,

1 (3) in subsection (g)(1), by striking out “: *Pro-*
2 *vided, however, That regulations*” and inserting in
3 lieu thereof a period and “Regulations”.

4 (4) in subsection (h), by striking out “507”.

5 (q) SECTION 508.—Subsections (c) and (e) of section
6 508 (21 U.S.C. 358) are each amended by striking out
7 “section 4 of the Administrative Procedure Act (5 U.S.C.
8 1003)” and inserting in lieu thereof “section 553 of title
9 5, United States Code”.

10 (r) SECTION 512.—Section 512 (21 U.S.C. 360b) is
11 amended—

12 (1) in subsection (c)(2)(A)(ii), by inserting “in”
13 after “provided”,

14 (2) in subsection (c)(2)(F)(i), by striking out
15 “(C)(iii)” and inserting in lieu thereof “(D)(iii)”,

16 (3) in subsection (c)(2)(H), by striking out
17 “subclause” the first time it appears and inserting
18 in lieu thereof “subclauses”,

19 (4) in subsection (d)(1), by striking out “sub-
20 paragraphs (A) through (G)” and inserting in lieu
21 thereof “subparagraphs (A) through (I)”, and

22 (5) in subsection (n)(1)—

23 (A) by striking out “201(w)” in subpara-
24 graphs (B)(ii)(II) and (C)(ii)(I) and inserting
25 in lieu thereof “201(v)”, and

1 (B) by striking out in the last sentence
2 “(H)” and inserting in lieu thereof “(I)”.

3 (s) SECTION 513.—Section 513(b)(3) (21 U.S.C.
4 360c(b)(3)) is amended by striking out “5703(b)” and in-
5 serting in lieu thereof “5703”.

6 (t) SECTION 515.—Section 515(c)(2)(A) (21 U.S.C.
7 360e(c)(2)(A)) is amended by striking out “refer such ap-
8 plication”.

9 (u) SECTION 519.—Section 519(a) (21 U.S.C.
10 360i(a)) is amended by striking out “paragraph (4)” and
11 inserting in lieu thereof “paragraph (7)”.

12 (v) SECTION 527.—Section 527(b) (21 U.S.C.
13 360cc(b)) is amended—

14 (1) by striking out “507,,” and inserting in lieu
15 thereof “507,,” and

16 (2) in paragraph (1), by striking out “The” and
17 inserting in lieu thereof “the”.

18 (w) SECTION 534.—Section 534(f)(2) (21 U.S.C.
19 360kk) is amended by striking out “this Act” and insert-
20 ing in lieu thereof “the Public Health Service Act”.

21 (x) SECTION 601.—Section 601(a) (21 U.S.C. 361)
22 is amended by striking out “: *Provided*, That this” and
23 inserting in lieu thereof “, except that this”.

24 (y) SECTION 701.—Section 701 (21 U.S.C. 371) is
25 amended—

1 (1) in subsection (e)(1), by striking out the pe-
2 riod after “Regulations)” the second time it occurs,
3 and

4 (2) in subsection (f)(4), by striking out “sec-
5 tions 239 and 240 of the Judicial Code, as amend-
6 ed” and inserting in lieu thereof “section 1254 of
7 title 28, United States Code”.

8 (z) SECTION 703.—Section 703 (21 U.S.C. 373) is
9 amended—

10 (1) by striking out “: *Provided, That*” and in-
11 serting in lieu thereof “, except that”,

12 (2) by striking out “: *Provided further, That*”
13 and inserting in lieu thereof “, and except that”

14 (aa) SECTION 704.—Section 704(a)(1) (21 U.S.C.
15 374(a)(1) is amended—

16 (1) by striking out the semicolon after “mate-
17 rials” and inserting in lieu thereof a comma, and

18 (2) by striking out “(j)” the first time it ap-
19 pears and inserting in lieu thereof “(k)”.

20 (bb) SECTION 721.—Section 721(b)(5)(D) (21
21 U.S.C. 379e(b)(5)(D)) is amended by striking out
22 “5703(b)” and inserting in lieu thereof “5703”.

23 (cc) SECTION 801.—Section 801(b) (21 U.S.C.
24 381(b) is amended—

1 (1) by striking out “Administrator” the first
2 time it occurs and inserting in lieu thereof “Sec-
3 retary of Health and Human Services”,

4 (2) by striking out “Administrator” the second
5 and third time it occurs and inserting in lieu thereof
6 “Secretary”,

7 (3) by striking out “Administrator’s” and in-
8 serting in lieu thereof “Secretary’s”, and

9 (4) by striking out “Federal Security Agency”
10 and inserting in lieu thereof “Department of Health
11 and Human Services”.

12 (dd) AGRICULTURE.—

13 (1) Sections 201(c), 201(d), 701(b), and 801(a)
14 (21 U.S.C. 321(c), 321(d), 371(b), and 381(a) are
15 each amended by striking out “Agriculture” each
16 place it appears and inserting in lieu thereof
17 “Health and Human Services”.

18 (2) Sections 702(c) and 706 (21 U.S.C. 372(c)
19 and 376) are each amended by striking out “of Agri-
20 culture” each place it appears.

21 **SEC. 4. TECHNICAL AMENDMENTS TO AMENDATORY ACTS.**

22 (a) SAFE MEDICAL DEVICES ACT OF 1990.—

23 (1) Section 18(b) of the Safe Medical Devices
24 Act of 1990 (Public Law 101-629) is amended by

1 striking out “(b)(4)(B)” and inserting in lieu thereof
2 “(b)”,

3 (2) Section 19(a)(4) of the Safe Medical De-
4 vices Act of 1990 (Public Law 101–629) is amend-
5 ed—

6 (A) by striking out “as amended by para-
7 graphs (1) and (2)” and inserting in lieu there-
8 of “as amended by paragraphs (1), (2), and
9 (3)”,

10 (B) by striking out “530” and inserting in
11 lieu thereof “531”, and

12 (C) by striking out “354” and inserting in
13 lieu thereof “355”.

14 (b) MEDICAL DEVICE AMENDMENTS OF 1992.—Sec-
15 tion 6(a) of the Medical Device Amendments of 1992
16 (Public Law 102–300) is amended by inserting “wherever
17 appearing” after “ ‘any of its principal’ ”.

18 (c) NUTRITION LABELING AND EDUCATION ACT OF
19 1990.—Section 8 of the Nutrition Labeling and Education
20 Act of 1990 is amended by striking the period at the end
21 and inserting close quotation marks and a period.

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