

114TH CONGRESS
1ST SESSION

S. 2301

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements related to nutrient information on food labels, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 18, 2015

Mr. BLUMENTHAL (for himself and Mr. MARKEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to strengthen requirements related to nutrient information on food labels, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food Labeling Modernization Act of 2015”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Additional requirements for front-of-packaging (FOP) labeling for processed foods.

- Sec. 3. Claims for conventional foods.
- Sec. 4. Use of specific terms.
- Sec. 5. Modernization of the Nutrition Facts Panel.
- Sec. 6. Ingredient labels.
- Sec. 7. Caffeine content on information panel.
- Sec. 8. Food allergen labeling for sesame.
- Sec. 9. Information about major food allergens in nonprepackaged foods.
- Sec. 10. Submission and availability of food label information.
- Sec. 11. Definitions.
- Sec. 12. Effective date; regulations.

1 **SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACK-**
 2 **AGING (FOP) LABELING FOR PROCESSED**
 3 **FOODS.**

4 (a) SUMMARY NUTRITION LABELING INFORMA-
 5 TION.—

6 (1) IN GENERAL.—Section 403 of the Federal
 7 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is
 8 amended by adding at the end the following new
 9 paragraph:

10 “(z)(1) Except as provided in subparagraphs (3), (4),
 11 and (5) of paragraph (q), if it is food (other than a dietary
 12 supplement) intended for human consumption and is of-
 13 fered for sale and otherwise required to bear nutrition la-
 14 beling, unless its principal display panel bears summary
 15 nutrition information that reflects the overall nutritional
 16 value of the food or specified ingredients, as specified in
 17 accordance with regulations of the Secretary, and does not
 18 contain any summary nutritional information which is in
 19 addition to or inconsistent with the information required
 20 under this subparagraph.”.

1 (2) PRINCIPLES FOR IMPLEMENTING REGULA-
2 TIONS.—In promulgating regulations regarding the
3 summary nutrition information required under the
4 amendment made by paragraph (1), the Secretary of
5 Health and Human Services shall take into account
6 published reports of the Institute of Medicine of the
7 National Academy of Sciences regarding such infor-
8 mation and base regulations on the following prin-
9 ciples:

10 (A) There should be a single simple, stand-
11 ard symbol system that displays calorie infor-
12 mation related to a common serving size, and
13 information related to nutrients strongly associ-
14 ated with public health concerns.

15 (B) Consumers should be able to quickly
16 and easily comprehend the meaning of the sym-
17 bol system as an indicator of a product's con-
18 tribution to a healthy diet.

19 (C) The information should appear on all
20 products that are required to bear nutrition la-
21 beling.

22 (D) The information should—

23 (i) appear in a consistent location on
24 the principal display panels across prod-
25 ucts;

(ii) have a prominent design that visually contrasts with existing packaging design; and

(iii) be sufficiently large to be easily legible.

(E) The nutrition information should be consistent with the Nutrition Facts Panel and with the recommendations of the Dietary Guidelines of Americans.

(F) The information should aim to facilitate consumer selection of healthy product options, including among nutritionally at-risk subpopulations.

(G) The Secretary should periodically evaluate the front-of-package information to assess its ability to help facilitate consumer selection of healthy product options and the extent to which manufacturers are offering healthier products as a result of the disclosure.

(H) The implementation of the information disclosure should be accompanied by appropriate consumer education and promotion campaigns determined by the Secretary.

(b) PERCENTAGE OF WHEAT AND GRAINS IN GRAIN-BASED PRODUCTS.—Section 403(z) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 343(z)), as added by
2 subsection (a)(1), is further amended by adding at the end
3 the following new subparagraph:

4 “(2) If, in the case of food other than a dietary
5 supplement, the principal display panel bears—

6 “(A) the phrase ‘made with whole grain’,
7 the term ‘multigrain’, or similar descriptive
8 phrases, terms, or representations with respect
9 to whole grain content, unless the amount of
10 whole grains, expressed as a percentage of total
11 grains, is conspicuously disclosed in immediate
12 proximity to such descriptive phrase, term, or
13 representation; or

14 “(B) the terms ‘wheat’ or ‘whole wheat’ on
15 breads, pasta, crackers, or similar wheat-based
16 products, unless the percentage of whole wheat
17 by weight contained in the food is conspicuously
18 declared in immediate proximity to that term or
19 there is a conspicuous declaration that the food
20 ‘contains no whole wheat’ in immediate prox-
21 imity to that term.”.

22 (c) SWEETENERS, COLORING, AND FLAVORING.—
23 Section 403(z) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 343(z)), as amended, is further amended
25 by adding at the end the following new subparagraph:

1 “(3) If, in the case of food other than a dietary
2 supplement, it bears or contains any added artificial
3 or natural coloring, any added artificial or natural
4 non-caloric sweetener, or any added artificial or nat-
5 ural flavoring, unless such fact is prominently stated
6 on the principal display panel of a package or con-
7 tainer of the food.”.

8 (d) CONFORMING AMENDMENT.—The second sen-
9 tence of section 403(k) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 343(k)) is amended by striking
11 “and (i)” and inserting “, (i), and (z)”.

12 (e) CONSTRUCTION.—Nothing in this section shall be
13 construed as affecting any requirement in regulation in
14 effect as of the date of the enactment of this Act with
15 respect to matters that are required to be stated on the
16 principal display panel of a package or container of food
17 that is not required by an amendment made by this section
18 or as restricting the authority of the Secretary of Health
19 and Human Services to require additional information be
20 disclosed on such a principal display panel.

21 **SEC. 3. CLAIMS FOR CONVENTIONAL FOODS.**

22 (a) HEALTH-RELATED CLAIMS.—

23 (1) REGULATIONS AND GUIDANCE.—Not later
24 than 3 years after the date of enactment of this Act,
25 the Secretary of Health and Human Services shall—

1 (A) promulgate a final rule clarifying the
 2 application of section 403(r) of the Federal
 3 Food, Drug, and Cosmetic Act (21 U.S.C.
 4 343(r)) with respect to the mechanisms by
 5 which a nutrient in food (other than a dietary
 6 supplement) is intended to affect the structure
 7 or any function of the human body, or charac-
 8 terize the documented mechanism by which a
 9 nutrient in such food acts to maintain such
 10 structure or function; and

11 (B) issue guidance clarifying the applica-
 12 tion of such section 403(r) with respect to the
 13 substantiation of claims pursuant to a request
 14 under section 403(r)(7) of such Act, as added
 15 by paragraph (2).

16 (2) SUBSTANTIATION OF CLAIM.—Section
 17 403(r) of the Federal Food, Drug, and Cosmetic Act
 18 (21 U.S.C. 343(r)) is amended—

19 (A) by redesignating subparagraph (7) as
 20 subparagraph (8); and

21 (B) by inserting after subparagraph (6)
 22 the following:

23 “(7) If the Secretary requests that a claim
 24 under subparagraph (1)(B) for food (other than a
 25 dietary supplement) be substantiated, then not later

1 than 90 days after the date on which the Secretary
 2 makes such request, the manufacturer shall provide
 3 to the Secretary all documentation in the manufac-
 4 turer’s possession relating to the claim.”.

5 (b) TRANS FATS.—Section 403(r)(2)(A) of the Fed-
 6 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 7 343(r)(2)(A)) is amended—

8 (1) in subclause (iii)—

9 (A) in the matter before item (I), by strik-
 10 ing “fat or saturated fat” and inserting “fat,
 11 saturated fat, or trans fats”; and

12 (B) in item (II), by striking “fat or satu-
 13 rated fat” and inserting “fat, saturated fat, or
 14 trans fats”;

15 (2) in subclause (iv), by striking “saturated
 16 fat” and inserting “saturated fat or trans fats” each
 17 place it appears;

18 (3) by redesignating subclauses (v) and (vi) as
 19 subclauses (vi) and (vii), respectively; and

20 (4) by inserting after subclause (iv) the fol-
 21 lowing new subclause:

22 “(v) may not be made with respect to the level
 23 of trans fats in the food unless the food contains less
 24 than one gram of saturated fat per serving or, if the
 25 food contains more than one gram of saturated fat

1 per serving, unless the label or labeling of the food
 2 discloses the level of saturated fat in the food in im-
 3 mediate proximity to such claim and with appro-
 4 priate prominence which shall be no less than one-
 5 half the size of the claim with respect to the level
 6 of trans fats,”.

7 (c) ADDED SUGARS.—Not more than 3 years after
 8 the date of enactment of this Act, the Secretary of Health
 9 and Human Services shall promulgate a final rule revising
 10 section 101.14 of title 21, Code of Federal Regulations,
 11 to include a disqualifying nutrient level for added sugars.

12 **SEC. 4. USE OF SPECIFIC TERMS.**

13 (a) USE OF THE TERM “NATURAL”.—

14 (1) IN GENERAL.—Not later than 2 years after
 15 the date of enactment of this Act, the Secretary of
 16 Health and Human Services shall promulgate a final
 17 rule—

18 (A) relating to use of the term “natural”
 19 on the labeling of food (other than a dietary
 20 supplement); and

21 (B) including provisions to specifically ad-
 22 dress the use of such term on the principal dis-
 23 play panel and the information panel.

1 (2) DEFINITION.—The rule promulgated pursu-
 2 ant to paragraph (1) shall define the term “nat-
 3 ural”—

4 (A) to exclude, at a minimum, the use of
 5 any artificial food or ingredient (including any
 6 artificial flavor or added color) or any synthetic
 7 substance; and

8 (B) based on data, including data on con-
 9 sumers’ understanding of the term as used in
 10 connection with food.

11 (3) PROCESS.—In promulgating the rule re-
 12 quired by paragraph (1), the Secretary of Health
 13 and Human Services shall—

14 (A) conduct consumer surveys and studies
 15 and issue a timely call for relevant public sub-
 16 missions regarding relevant consumer research,
 17 including with respect to consumer under-
 18 standing of the term “natural” in relation to
 19 the term “organic”; and

20 (B) fully consider the results of such sur-
 21 veys and studies, as well as such public submis-
 22 sions.

23 (b) USE OF TERM “HEALTHY”.—

24 (1) ADDED SUGARS AND WHOLE GRAINS.—The
 25 Secretary of Health and Human Services shall revise

1 the regulations under the Federal Food, Drug, and
 2 Cosmetic Act relating to the use of the term
 3 “healthy” on the labeling of a food (other than a di-
 4 etary supplement) to take into account the extent to
 5 which such food contains added sugars or whole
 6 grains.

7 (2) REQUIREMENTS.—In making the revisions
 8 to regulations required by paragraph (1)—

9 (A) in the case of a food (other than a die-
 10 tary supplement) that contains grains, the Sec-
 11 retary shall not consider the food to be
 12 “healthy” unless at least half of those grains,
 13 by weight, are whole grains; and

14 (B) the Secretary shall not allow a food to
 15 be labeled “healthy” if the food contains more
 16 than 10 percent of the daily value of added
 17 sugar per serving as determined by the Sec-
 18 retary under section 403(q)(1)(F)(i) of the Fed-
 19 eral Food, Drug, and Cosmetic Act, as added
 20 by section 5(c) of this Act.

21 **SEC. 5. MODERNIZATION OF THE NUTRITION FACTS PANEL.**

22 (a) DISCLOSURE OF CALORIE INFORMATION.—Sec-
 23 tion 403(q)(1) of the Federal Food, Drug, and Cosmetic
 24 Act (21 U.S.C. 343(q)(1)) is amended—

1 (1) by striking the period at the end of clause
2 (E) and inserting a comma;

3 (2) by inserting after clause (E) the following
4 new clause:

5 “(F) in the case of food other than a die-
6 tary supplement—

7 “(i) the percent of recommended daily
8 calories that are provided by one serving of
9 the product, based on a recommended daily
10 consumption of calories determined by the
11 Secretary to be appropriate for members of
12 the general population; and

13 “(ii) at the discretion of the Sec-
14 retary, the percent of recommended daily
15 calories that are provided by one serving of
16 the product—

17 “(I) for members of any sub-
18 population identified by the Secretary;
19 and

20 “(II) based on a recommended
21 daily consumption of calories deter-
22 mined by the Secretary to be appro-
23 priate for members of such subpopula-
24 tion, and”; and

1 (3) by adding, after the flush text following
 2 clause (F), as added by paragraph (2), the following:
 3 “The information required under clause (C)(i) shall,
 4 in the case of food other than a dietary supplement,
 5 appear in a typeface and design which is more
 6 prominent and conspicuous than that used for other
 7 information required under this subparagraph.”.

8 (b) SERVING SIZE.—Section 403(q)(1)(A)(i) of the
 9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 10 343(q)(1)(A)(i)) is amended by inserting “, or, in the case
 11 of a food (other than a dietary supplement) that is pack-
 12 aged in an amount that could reasonably be consumed in
 13 a single-eating occasion, which is an amount equal to the
 14 amount of food contained in the package” before “, or”.

15 (c) DISCLOSURE OF INFORMATION RELATING TO
 16 SUGAR ON NUTRITION FACT PANEL.—

17 (1) IN GENERAL.—Section 403(q)(1) of the
 18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 19 343(q)(1)), as amended by subsection (a), is amend-
 20 ed—

21 (A) in subparagraph (D), by striking “sug-
 22 ars” and inserting “sugars (and, in the case of
 23 food other than a dietary supplement, total sug-
 24 ars, and of that, added sugars, disclosed in
 25 teaspoons as well as grams)”; and

1 (B) by inserting after clause (F), as added
 2 by subsection (a)(2), the following new clause:

3 “(G) in the case of food other than a die-
 4 tary supplement—

5 “(i) the percent of added sugars rec-
 6 ommended for daily consumption that are
 7 provided by one serving of the product,
 8 based on a recommended daily consump-
 9 tion of calories determined by the Sec-
 10 retary to be appropriate for members of
 11 the general population; and

12 “(ii) at the discretion of the Sec-
 13 retary, the percent of added sugars rec-
 14 ommended for daily consumption that are
 15 provided by one serving of the product—

16 “(I) for members of any sub-
 17 population identified by the Secretary;
 18 and

19 “(II) based on a recommended
 20 daily consumption of calories deter-
 21 mined by the Secretary to be appro-
 22 priate for members of such subpopula-
 23 tion.”.

24 **SEC. 6. INGREDIENT LABELS.**

25 (a) **FORMAT OF INGREDIENT LABELS.—**

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall include requirements for the
3 format of the information required under section
4 403(i) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 343(i))—

6 (A) for the purpose of improving the read-
7 ability of such information on the label of the
8 food (other than a dietary supplement); and

9 (B) that are, as determined by the Sec-
10 retary, necessary to assist consumers in main-
11 taining healthy dietary practices.

12 (2) FORMAT REQUIREMENTS.—The format re-
13 quirements referred to in paragraph (1) shall include
14 requirements for upper- and lower-case characters,
15 serif and noncondensed font types, high-contrast be-
16 tween text and background, and bullet points be-
17 tween adjacent ingredients with appropriate exemp-
18 tions for small packages or other considerations.

19 (b) CHARACTERIZING INGREDIENTS IN NAME OR
20 PRIMARY DISPLAY PANEL.—

21 (1) IN GENERAL.—Section 403 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 343), as
23 amended by section 2(a)(1), is further amended by
24 adding at the end the following new paragraph:

1 “(aa) If the name or primary display panel of the
 2 food (other than a dietary supplement) refers to any char-
 3 acterizing ingredient or component of the food, unless—

4 “(1) the characterizing ingredient or component
 5 is a predominant ingredient in the food; or

6 “(2) the primary display panel of the food in-
 7 cludes, in letters not less than one-half the height of
 8 the letters used in the name of the food, the percent-
 9 age of the characterizing ingredient or component
 10 contained in each serving of the food.”.

11 (2) ENFORCEMENT OF CHARACTERIZING IN-
 12 GREDIENTS.—Not later than 2 years after the date
 13 of enactment of this Act and every 2 years there-
 14 after, the Secretary of Health and Human Services
 15 shall submit a report to Congress on the Secretary’s
 16 enforcement of—

17 (A) section 403(aa) of the Federal Food,
 18 Drug, and Cosmetic, as added by paragraph
 19 (1); and

20 (B) regulations of the Food and Drug Ad-
 21 ministration on characterizing ingredients and
 22 components including section 102.5 of title 21,
 23 Code of Federal Regulations (and any successor
 24 regulations).

1 **SEC. 7. CAFFEINE CONTENT ON INFORMATION PANEL.**

2 Section 403(i) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 343(i)) is amended—

4 (1) by striking “and (2)” and inserting “(2)”;

5 (2) by striking “and if the food purports” and
6 inserting “, (3) if the food purports”; and

7 (3) by inserting “, and (4) if the food is food
8 other than a dietary supplement and contains at
9 least 10 milligrams of caffeine from all sources per
10 serving, a statement (with appropriate prominence
11 near the statement of ingredients required by this
12 paragraph) of the number of milligrams of caffeine
13 contained in one serving of the food and the size of
14 such serving” after “vegetable juice contained in the
15 food”.

16 **SEC. 8. FOOD ALLERGEN LABELING FOR SESAME.**

17 (a) DEFINITION OF MAJOR FOOD ALLERGEN.—Sec-
18 tion 201(qq)(1) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 321(qq)(1)) is amended by striking “and
20 soybeans” and inserting “soybeans, and sesame”.

21 (b) REGULATION.—Not later than 3 years after the
22 date of enactment of this Act, the Secretary of Health and
23 Human Services shall promulgate a final regulation under
24 section 403(w) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 343(w)) determining the manner in which
26 sesame must be disclosed.

1 **SEC. 9. INFORMATION ABOUT MAJOR FOOD ALLERGENS IN**
 2 **NONPREPACKAGED FOODS.**

3 (a) IN GENERAL.—Section 403(w) of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 343(w)) is
 5 amended—

6 (1) in subparagraph (1)(A), by striking “is
 7 printed immediately after or is adjacent to the list
 8 of ingredients (in a type size no smaller than the
 9 type size used in the list of ingredients) required
 10 under subsections (g) and (i)” and inserting “is
 11 printed as specified in subparagraph (8)”;

12 (2) in subparagraph (1)(B), by striking “in the
 13 list of ingredients required under subsections (g)
 14 and (i)” and inserting “as so printed”;

15 (3) in subparagraph (3), by striking “The infor-
 16 mation” and inserting “Subject to subparagraph
 17 (8)(B), the information”; and

18 (4) by adding at the end the following:

19 “(8) The information required by subparagraph (1)
 20 to be conveyed to the consumer shall be—

21 “(A) printed immediately after or adjacent to
 22 the list of ingredients (in a type size no smaller than
 23 the type size used in the list of ingredients) required
 24 under subsections (g) and (i); or

25 “(B) in the case of a nonpackaged food being
 26 offered for sale at retail, and not subject to the re-

(b) APPLICABILITY.—The amendments made by sub-
section (a) apply beginning on the date that is 3 years
after the date of enactment of this Act.

9 The Federal Food, Drug, and Cosmetic Act is amend-
10 ed by inserting after section 403C of such Act (21 U.S.C.
11 343–3) the following:

14 “(a) SUBMISSIONS.—

“(1) REQUIREMENT.—The Secretary shall require the manufacturer or importer of any food that is introduced or delivered for introduction into interstate commerce in package form to submit to the Secretary all information to be included in the label of the food, including—

21 “(A) the nutrition facts panel;

22 “(B) ingredients;

23 “(C) any natural or artificial flavoring;

24 “(D) an image of the primary display
25 panel;

1 “(E) allergy warnings or information;

2 “(F) claims under section 403(r)(1)(A)
3 (popularly referred to as ‘nutrient-content
4 claims’);

5 “(G) claims under section 403(r)(1)(B)
6 (popularly referred to as ‘health-related
7 claims’); and

8 “(H) other relevant information as deter-
9 mined by the Secretary.

10 “(2) UPDATES.—The Secretary shall require
11 the manufacturer or importer of food to update or
12 supplement the information submitted under para-
13 graph (1) with respect to the food in order to keep
14 the information up-to-date and complete.

15 “(3) CIVIL PENALTY.—Whoever knowingly vio-
16 lates paragraph (1) with respect to any food shall be
17 liable to the United States for a civil penalty in an
18 amount not to exceed \$10,000 for each day on which
19 such violation continues with respect to such food.

20 “(b) PUBLIC DATABASE.—The Secretary shall estab-
21 lish and maintain a public database containing the infor-
22 mation submitted under this section that—

23 “(1) is available to the public through the
24 Internet website of the Food and Drug Administra-
25 tion; and

1 “(2) is for a public database of searchable, sort-
2 able information.”.

3 **SEC. 11. DEFINITIONS.**

4 (a) DEFINITIONS APPLICABLE IN THIS ACT.—In this
5 Act, the terms “food” and “dietary supplement” have the
6 meanings given to such terms in section 201 of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321).

8 (b) DEFINITIONS APPLICABLE IN THE FEDERAL
9 FOOD, DRUG, AND COSMETIC ACT.—Section 201 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)
11 is amended by adding at the end the following:

12 “(ss) The term ‘artificial’, with respect to food or any
13 ingredient of food, means—

14 “(1) food or an ingredient that is synthetically
15 produced but has the same chemical structure as a
16 naturally occurring food or ingredient;

17 “(2) food or an ingredient that has undergone
18 chemical changes through the introduction of syn-
19 thetic chemicals or processing aids (such as corn
20 syrup, high-fructose corn syrup, high-maltose corn
21 syrup, maltodextrin, chemically modified starch, and
22 cocoa processed with alkali), excluding—

23 “(A) food or an ingredient that has under-
24 gone traditional processes used to make food
25 edible, to preserve food, or to make food safe

1 for human consumption (such as smoking,
2 roasting, freezing, drying, and fermenting proc-
3 esses); or

4 “(B) food or ingredient that has undergone
5 traditional physical processes that do not fun-
6 damentally alter the raw product or which only
7 separate a whole intact food into component
8 parts (such as grinding grains, separating eggs
9 into albumen and yolk, or pressing fruits to
10 produce juice); or

11 “(3) any food or ingredient that the Secretary
12 specifies by regulation to be artificial for purposes of
13 this Act.

14 “(tt) The term ‘synthetic’, with respect to a sub-
15 stance, means a substance that is formulated or manufac-
16 tured by a chemical process or by a process that chemi-
17 cally changes a substance extracted from a naturally oc-
18 ccurring plant, animal, or mineral source, except that such
19 term does not apply to a substance created by naturally
20 occurring biological processes.”.

21 **SEC. 12. EFFECTIVE DATE; REGULATIONS.**

22 (a) EFFECTIVE DATE.—The amendments made by—
23 (1) sections 3, 4, 5, 6, 7, 10, and 11(b) shall
24 take effect on the date that is 2 years after the date
25 of enactment of this Act; and

1 (2) sections 2 and 9 shall take effect on the
2 date that is 3 years after such date of enactment.

3 (b) REGULATIONS.—

4 (1) PROPOSED REGULATIONS.—The Secretary
5 of Health and Human Services shall propose regula-
6 tions—

7 (A) not later than 1 year after the date of
8 enactment of this Act, to implement the amend-
9 ments made by sections 3, 4, 5, 6, 7, 9, 10, and
10 11(b); and

11 (B) not later than 2 years after such date
12 of enactment, to implement the amendments
13 made by section 2.

14 (2) FINAL REGULATIONS.—The Secretary of
15 Health and Human Services shall promulgate final
16 regulations—

17 (A) not later than 2 years after such date
18 of enactment, to implement the amendments
19 made by sections 3, 4, 5, 6, 7, 9, 10, and 11(b);
20 and

21 (B) not later than 3 years after such date
22 of enactment to implement the amendments
23 made by section 2.

24 (3) DEADLINE.—If the Secretary of Health and
25 Human Services does not issue a final regulation by

1 the deadline specified in subparagraph (A) or (B) of
2 paragraph (2), the corresponding proposed regula-
3 tion under subparagraph (A) or (B) of paragraph
4 (1) shall become final on the respective deadline.

○