

114TH CONGRESS
1ST SESSION

H. R. 4061

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 HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2015

Mr. PALLONE (for himself and Ms. DELAURO) introduced the following bill;
which was referred to the Committee on Energy and Commerce

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 sup-
5 plement, the principal display panel bears—

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

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

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

24 “(3) If, in the case of food other than a dietary sup-
25 plement, it bears or contains any added artificial or nat-

1 ural coloring, any added artificial or natural non-caloric
2 sweetener, or any added artificial or natural flavoring, un-
3 less such fact is prominently stated on the principal dis-
4 play panel of a package or container of the food.”.

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

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

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

19 (a) HEALTH-RELATED CLAIMS.—

20 (1) REGULATIONS AND GUIDANCE.—Not later
21 than three years after the date of enactment of this
22 Act, the Secretary of Health and Human Services
23 shall—

24 (A) promulgate a final rule clarifying the
25 application of section 403(r) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)) with respect to the mechanisms by which a nutrient in food (other than a dietary supplement) is intended to affect the structure or any function of the human body, or characterize the documented mechanism by which a nutrient in such food acts to maintain such structure or function; and

(B) issue guidance clarifying the application of such section 403(r) with respect to the substantiation of claims pursuant to a request under section 403(r)(7) of such Act, as added by paragraph (2).

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

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

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

“(7) If the Secretary requests that a claim under subparagraph (1)(B) for food (other than a dietary supplement) be substantiated, then not later than 90 days after the date on which the Secretary makes such request, the manufacturer shall provide

1 to the Secretary all documentation in the manufac-
2 turer's possession relating to the claim.”.

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

6 (1) in subclause (iii)—

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

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

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

16 (3) by redesignating subclauses (v) and (vi) as
17 subclauses (vi) and (vii), respectively; and

18 (4) by inserting after subclause (iv) the fol-
19 lowing new subclause:

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

1 mediate proximity to such claim and with appro-
2 priate prominence which shall be no less than one-
3 half the size of the claim with respect to the level
4 of trans fats,”.

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

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

11 (a) USE OF THE TERM “NATURAL”.—

12 (1) IN GENERAL.—Not later than two years
13 after the date of enactment of this Act, the Sec-
14 retary of Health and Human Services shall promul-
15 gate a final rule—

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

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

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

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

5 (B) based on data, including data on con-
6 sumers' understanding of the term as used in
7 connection with food.

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

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

17 (B) fully consider the results of such sur-
18 veys and studies, as well as such public submis-
19 sions.

20 (b) USE OF TERM “HEALTHY”.—

21 (1) ADDED SUGARS AND WHOLE GRAINS.—The
22 Secretary of Health and Human Services shall revise
23 the regulations under the Federal Food, Drug, and
24 Cosmetic Act relating to the use of the term
25 “healthy” on the labeling of a food (other than a di-

etary supplement) to take into account the extent to which such food contains added sugars or whole grains.

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

(A) in the case of a food (other than a dietary supplement) that contains grains, the Secretary shall not consider the food to be “healthy” unless at least half of those grains, by weight, are whole grains; and

(B) the Secretary shall not allow a food to be labeled “healthy” if the food contains more than 10 percent of the daily value of added sugar per serving as determined by the Secretary under section 403(q)(1)(F)(i) of the Federal Food, Drug, and Cosmetic Act, as added by section 5(c) of this Act.

SEC. 5. MODERNIZATION OF THE NUTRITION FACTS PANEL.

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

(1) by striking the period at the end of clause

(E) and inserting a comma;

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

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

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

9 “(ii) at the discretion of the Sec-
10 retary, the percent of recommended daily
11 calories that are provided by one serving of
12 the product—

13 “(I) for members of any sub-
14 population identified by the Secretary;
15 and

16 “(II) based on a recommended
17 daily consumption of calories deter-
18 mined by the Secretary to be appro-
19 priate for members of such subpopula-
20 tion.”; and

21 (3) by adding, after the flush text following
22 clause (F), as added by paragraph (2), the following:
23 “The information required under clause (C)(i) shall,
24 in the case of food other than a dietary supplement,
25 appear in a typeface and design which is more

1 prominent and conspicuous than that used for other
 2 information required under this subparagraph.”.

3 (b) SERVING SIZE.—Section 403(q)(1)(A)(i) of the
 4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 5 343(q)(1)(A)(i)) is amended by inserting “, or, in the case
 6 of a food (other than a dietary supplement) that is pack-
 7 aged in an amount that could reasonably be consumed in
 8 a single-eating occasion, which is an amount equal to the
 9 amount of food contained in the package” before “, or”.

10 (c) DISCLOSURE OF INFORMATION RELATING TO
 11 SUGAR ON NUTRITION FACT PANEL.—

12 (1) IN GENERAL.—Section 403(q)(1) of the
 13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 14 343(q)(1)), as amended by subsection (a), is amend-
 15 ed—

16 (A) in subparagraph (D), by striking “sug-
 17 ars” and inserting “sugars (and, in the case of
 18 food other than a dietary supplement, total sug-
 19 ars, and of that, added sugars, disclosed in
 20 teaspoons as well as grams)”;

21 (B) by inserting after clause (F) the fol-
 22 lowing new clause:

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

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

8 “(ii) at the discretion of the Sec-
9 retary, the percent of added sugars rec-
10 ommended for daily consumption that are
11 provided by one serving of the product—

12 “(I) for members of any sub-
13 population identified by the Secretary;
14 and

15 “(II) based on a recommended
16 daily consumption of calories deter-
17 mined by the Secretary to be appro-
18 priate for members of such subpopula-
19 tion.”.

20 **SEC. 6. INGREDIENT LABELS.**

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

22 (1) **IN GENERAL.—**The Secretary of Health and
23 Human Services shall include requirements for the
24 format of the information required under section

1 403(i) of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 343(i))—

3 (A) for the purpose of improving the read-
4 ability of such information on the label of the
5 food (other than a dietary supplement); and

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

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

16 (b) CHARACTERIZING INGREDIENTS IN NAME OR
17 PRIMARY DISPLAY PANEL.—

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

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

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

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

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

14 (A) section 403(aa) of the Federal Food,
15 Drug, and Cosmetic, as added by paragraph
16 (1); and

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

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

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

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

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

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

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

17 (b) REGULATION.—Not later than 3 years after the
18 date of enactment of this Act, the Secretary of Health and
19 Human Services shall promulgate a final regulation under
20 section 403(w) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 343(x)) determining the manner in which
22 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-

7 SEC. 10. SUBMISSION AND AVAILABILITY OF FOOD LABEL
8 INFORMATION.

12 "SEC. 403D. SUBMISSION AND AVAILABILITY OF FOOD
13 LABEL INFORMATION.

“(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—

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 website of the Food and Drug Administration; 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 curring 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.

○