(Original Signature of Member)

113TH CONGRESS 1ST SESSION



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

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

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 2013".
- 6 (b) TABLE OF CONTENTS.—The table of contents of
- 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.

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Sec.	2.	Additional requirements	for	front-of-packaging	(FOP)	labeling for	proc-
		essed 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. Effective date; regulations.
- Sec. 9. Definitions.

SEC. 2. ADDITIONAL REQUIREMENTS FOR FRONT-OF-PACK AGING (FOP) LABELING FOR PROCESSED
 FOODS.
 (a) SUMMARY NUTRITION LABELING INFORMA-

5 TION.—

6 (1) IN GENERAL.—Section 403 of 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 labeling, unless its principal display panel bears summary 14 15 nutrition information that reflects the overall nutritional value of the food or specified ingredients, as specified in 16 17 accordance with regulations of the Secretary, and does not contain any summary nutritional information which 18 is in addition to or inconsistent with the information re-19 quired under this subparagraph.". 20

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;

1	(ii) have a prominent design that vis-
2	ually contrasts with existing packaging de-
3	sign; and
4	(iii) be sufficiently large.
5	(E) The nutrition information should be
6	consistent with the Nutrition Facts Panel and
7	with the recommendations of the Dietary
8	Guidelines of Americans.
9	(F) The information should aim to facili-
10	tate consumer selection of healthy product op-
11	tions, including among nutritionally at-risk sub-
12	populations.
13	(G) The Secretary should periodically
14	evaluate the front-of-package information to as-
15	sess its ability to help facilitate consumer selec-
16	tion of healthy product options and the extent
17	to which manufacturers are offering healthier
18	products as a result of the disclosure.
19	(H) The implementation of the information
20	disclosure should be accompanied by appro-
21	priate consumer education and promotion cam-
22	paigns determined by the Secretary.
23	(b) Percentage of Wheat and Grains in Grain-
24	BASED PRODUCTS.—Section 403(z) of Federal Food,
25	Drug, and Cosmetic Act (21 U.S.C. 343(z)), as added by

subsection (a)(1), is further amended by adding at the end
 the following new subparagraph:

- 3 "(2) If, in the case of food other than a dietary sup-4 plement, the principal display panel bears—
- 5 "(A) the phrase 'made with whole grain', the 6 term 'multigrain', or similar descriptive phrases, 7 terms, or representations with respect to whole grain 8 content, unless the amount of whole grains, ex-9 pressed as a percentage of total grains, is conspicu-10 ously disclosed in immediate proximity to such de-11 scriptive phrase, term, or representation; or
- 12 "(B) the terms 'wheat' or 'whole wheat' on 13 breads, pasta, crackers, or similar wheat-based prod-14 ucts, unless the percentage of whole wheat by weight 15 contained in the food is conspicuously declared in 16 immediate proximity to that term or there is a con-17 spicuous declaration that the food 'contains no whole 18 wheat' in immediate proximity to that term.".

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

"(3) If, in the case of food other than a dietary supplement, it bears or contains any added artificial or natural coloring, any added artificial or natural non-caloric

sweetener, or any added artificial or natural flavoring, un less such fact is prominently stated on the principal dis play panel of a package or container of the food.".

4 (d) CONFORMING AMENDMENT.—The second sen5 tence of section 403(k) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 343(k)) is amended by striking
7 "and (i)" and inserting ", (i), and (z)".

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

17 SEC. 3. CLAIMS FOR CONVENTIONAL FOODS.

18 (a) STRUCTURE AND FUNCTION CLAIMS.—

(1) GUIDANCE.—Not later than one year after
the date of enactment of this Act, the Secretary of
Health and Human Services shall issue comprehensive guidance clarifying the 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

1	supplement) is intended to affect the structure or
2	any function of the human body, or characterize the
3	documented mechanism by which a nutrient in such
4	food acts to maintain such structure or function.
5	(2) SUBSTANTIATION OF CLAIM.—Section
6	403(r) of Federal Food, Drug, and Cosmetic Act
7	(21 U.S.C. 343(r)) is amended—
8	(A) by redesignating subparagraph (7) as
9	subparagraph (8); and
10	(B) by inserting after subparagraph (6)
11	the following:
12	((7) If the Secretary requests that a claim
13	under paragraph $(r)(1)(B)$ for food (other than a di-
14	etary supplement) be substantiated, then not later
15	than 90 days after the date on which the Secretary
16	makes such request, the manufacturer shall provide
17	to the Secretary all documentation in the manufac-
18	turer's possession relating to the claim.".
19	(b) Trans Fats.—Section 403(r)(2)(A) of Federal
20	Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(2)(A))
21	is amended—
22	(1) in subclause (iii)—
23	(A) in the matter before item (I), by strik-
24	ing "fat or saturated fat" and inserting "fat,
25	saturated fat, or trans fats"; and

1	(B) in item (II), by striking "fat or satu-
2	rated fat" and inserting "fat, saturated fat, or
3	trans fats";
4	(2) in subclause (iv), by striking "saturated
5	fat" and inserting "saturated fat or trans fats" each
6	place it appears;
7	(3) by redesignating subclauses (v) and (vi) as
8	subclauses (vi) and (vii), respectively; and
9	(4) by inserting after subclause (iv) the fol-
10	lowing new subclause:
11	"(v) may not be made with respect to the level
12	of trans fats in the food unless the food contains less
13	than one gram of saturated fat per serving or, if the
14	food contains more than one gram of saturated fat
15	per serving, unless the label or labeling of the food
16	discloses the level of saturated fat in the food in im-
17	mediate proximity to such claim and with appro-
18	priate prominence which shall be no less than one-
19	half the size of the claim with respect to the level
20	of trans fats,".
21	SEC. 4. USE OF SPECIFIC TERMS.
22	(a) Use of the Term "Natural".—Section 403
23	of Federal Food, Drug, and Cosmetic Act (21 U.S.C.

24 343), as amended by section 2, is further amended by add-25 ing at the end the following new paragraph:

"(aa) If, in the case of food other than a dietary sup plement, the label bears the term 'natural' and the food
 contains any artificial ingredient (including any artificial
 flavor or artificial color), including—

5 "(1) any ingredient that is synthesized but has
6 the same chemical structure as a naturally occurring
7 ingredient;

8 "(2) any ingredient that has undergone chem-9 ical changes, such as corn syrup, high-fructose corn 10 syrup, high-maltose corn syrup, maltodextrin, chemi-11 cally modified starch, cocoa processed with alkali, 12 but not including—

13 "(A) food that has undergone traditional
14 processes used to make food edible, to preserve
15 food, or to make food safe for human consump16 tion (such as smoking, roasting, freezing, dry17 ing, and fermenting processes); or

18 "(B) food that has undergone traditional 19 physical processes that do not fundamentally 20 alter the raw product or which only separate a 21 whole intact food into component parts (such as 22 grinding grains, separating eggs into albumen 23 and yolk, or pressing fruits to produce juice); or 24 "(3) any other artificially-created ingredient 25 that the Secretary specifies in regulations.".

(b) USE OF TERM "HEALTHY".—The Secretary of 1 2 Health and Human Services shall revise the regulations under the Federal Food, Drug, and Cosmetic Act relating 3 to the use of the term "healthy" on the label of a food 4 5 (other than a dietary supplement) to take into account the extent to which such food contains added sugars or whole 6 7 grains. In the case of a food (other than a dietary supple-8 ment) that contains grains, in revising such regulations, the Secretary shall not consider the food to be "healthy" 9 unless at least half of those grains, by weight, are whole 10 11 grains.

12 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—

16 (1) by striking the period at the end the clause17 (E) and inserting a comma;

18 (2) by inserting after clause (E) the following19 new clause:

20 "(F) in the case of food other than a die21 tary supplement—

"(i) the percent of recommended daily
calories that are provided by one serving of
the product, based on a recommended daily
consumption of calories determined by the

1	Secretary to be appropriate for members of
2	the general population; and
3	"(ii) at the discretion of the Sec-
4	retary, the percent of recommended daily
5	calories that are provided by one serving of
6	the product—
7	"(I) for members of any sub-
8	population identified by the Secretary;
9	and
10	"(II) based on a recommended
11	daily consumption of calories deter-
12	mined by the Secretary to be appro-
13	priate for members of such subpopula-
14	tion."; and
15	(3) by adding, after the flush text following
16	clause (F), as added by paragraph (2), the following:
17	"The information required under clause (C)(i) shall,
18	in the case of food other than a dietary supplement,
19	appear in a typeface and design which is more
20	prominent and conspicuous than that used for other
21	information required under this subparagraph.".
22	(b) SERVING SIZE.—Section 403(q)(1)(A)(i) of Fed-
23	eral Food, Drug, and Cosmetic Act (21 U.S.C.
24	343(q)(1)(A)(i) is amended by inserting ", or, in the case
25	of a food (other than a dietary supplement) that is pack-

1	aged in an amount that could reasonably be consumed in
2	a single-eating occasion, which is an amount equal to the
3	amount of food contained in the package" before ", or".
4	(c) DISCLOSURE OF INFORMATION RELATING TO
5	SUGAR ON NUTRITION FACT PANEL.—
6	(1) IN GENERAL.—Section 403(q)(1) of Federal
7	Food, Drug, and Cosmetic Act (21 U.S.C.
8	343(q)(1)), as amended by subsection (a), is amend-
9	ed—
10	(A) in subparagraph (D), by striking "sug-
11	ars" and inserting "sugars (and, in the case of
12	food other than a dietary supplement, total sug-
13	ars, and, of that, added sugars)"; and
14	(B) by inserting after clause (F) the fol-
15	lowing new clause:
16	"(G) in the case of food other than a die-
17	tary supplement—
18	"(i) the percent of added sugars rec-
19	ommended for daily consumption that are
20	provided by one serving of the product,
21	based on a recommended daily consump-
22	tion of calories determined by the Sec-
23	retary to be appropriate for members of
24	the general population; and

1	"(ii) at the discretion of the Sec-
2	retary, the percent of added sugars rec-
3	ommended for daily consumption that are
4	provided by one serving of the product—
5	"(I) for members of any sub-
6	population identified by the Secretary;
7	and
8	"(II) based on a recommended
9	daily consumption of calories deter-
10	mined by the Secretary to be appro-
11	priate for members of such subpopula-
12	tion.".

13 SEC. 6. INGREDIENT LABELS.

(a) GROUPING OF SUGARS, NON-CALORIC SWEETENERS, AND SUGAR ALCOHOLS FOR ORDERING OF PREDOMINANCE.—Section 403 of the Federal Food, Drug,
and Cosmetic Act (21 U.S.C. 343), as amended by sections 2 and 4, is amended by adding at the end the following new paragraph:

20 "(bb) In case it is food other than a dietary supple21 ment and is fabricated from two or more ingredients, un22 less—

23 "(A) any sugars, non-caloric sweeteners, or
24 sugar alcohols are each treated as a group in the list
25 of ingredients on the label, including for purposes of

1	determining the order of predominance of ingredi-
2	ents; and
3	"(B) individual sugars, non-caloric sweeteners,
4	and sugar alcohols are listed parenthetically within
5	each such group in their order of predominance
6	within the group.".
7	(b) Format of Ingredient Labels.—
8	(1) IN GENERAL.—The Secretary of Health and
9	Human Services shall include requirements for the
10	format of the information required under section
11	403(i) of the Federal Food, Drug, and Cosmetic Act
12	(21 U.S.C. 343(i))—
13	(A) for the purpose of improving the read-
14	ability of such information on the label of the
15	food (other than a dietary supplement); and
16	(B) that are, as determined by the Sec-
17	retary, necessary to assist consumers in main-
18	taining healthy dietary practices.
19	(2) FORMAT REQUIREMENTS.—The format re-
20	quirements referred to in paragraph (1) shall include
21	requirements for upper- and lower-case characters,
22	serif and noncondensed font types, high-contrast be-
23	tween text and background, and bullet points be-
24	tween adjacent ingredients with appropriate exemp-
25	tions for small packages or other considerations.

1 SEC. 7. CAFFEINE CONTENT ON INFORMATION PANEL.

2 Section 403(i) of the Federal Food, Drug, and Cos3 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

(3) by inserting ", and (4) if the food is food 7 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 food". 15

16 SEC. 8. EFFECTIVE DATE; REGULATIONS.

(a) EFFECTIVE DATE.—The amendments made by—
(1) sections 3 through 7 shall take effect on the
date that is 2 years after the date of enactment of
this Act; and

21 (2) section 2 shall take effect on the date that22 is 3 years after such date of enactment.

23 (b) REGULATIONS.—

24 (1) PROPOSED REGULATIONS.—The Secretary
25 of Health and Human Services shall propose regula26 tions—

1	(A) not later than 1 year after the date of
2	enactment of this Act, to implement the amend-
3	ments made by sections 3 through 7; and
4	(B) not later than 2 years after such date
5	of enactment, to implement the amendments
6	made by section 2.
7	(2) FINAL REGULATIONS.—The Secretary of
8	Health and Human Services shall promulgate final
9	regulations—
10	(A) not later than 2 years after such date
11	of enactment, to implement the amendments
12	made by sections 3 through 7; and
13	(B) not later than 3 years after such date
14	of enactment to implement the amendments
15	made by section 2.
16	(3) DEADLINE.—If the Secretary of Health and
17	Human Services does not issue a final regulation by
18	the deadline specified in subparagraph (A) or (B) of
19	paragraph (2), the corresponding proposed regula-
20	tion under subparagraph (A) or (B) of paragraph
21	(1) shall become final on the respective deadline.
22	SEC. 9. DEFINITIONS.
23	In this Act, the terms "food" and "dietary supple-
24	ment" have the meanings given to such terms in section

- $1\ \ 201$ of the Federal Food, Drug, and Cosmetic Act (21
- 2 U.S.C. 321).