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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the product meets certain standards, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. SEAN PATRICK MALONEY of New York introduced the following bill;
which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to treat as misbranded cosmetics with packaging or labeling using the term “natural” unless the product meets certain standards, 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 “Natural Cosmetics
5 Act”.

1 **SEC. 2. COSMETICS WITH CERTAIN TERMS MISBRANDED.**

2 (a) IN GENERAL.—Section 602 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 362) is amended by
4 adding at the end the following:

5 “(g) If its packaging or labeling bears the term ‘nat-
6 ural’ unless—

7 “(1) if the term ‘natural’ pertains to the cos-
8 metic overall, the cosmetic contains—

9 “(A) at least 70 percent natural sub-
10 stances (other than water and salt);

11 “(B) no fragrance ingredient other than a
12 natural substance or naturally-derived ingre-
13 dient; and

14 “(C) other than natural substances and
15 water, contains only naturally-derived ingredi-
16 ents except to the extent a naturally-derived in-
17 gredient—

18 “(i) is not available for a specific
19 function; or

20 “(ii) is otherwise not feasible;

21 “(2) if the term ‘natural’ pertains to one or
22 more ingredients in the cosmetic—

23 “(A) the ingredient statement identifies
24 natural ingredients individually with the terms
25 ‘natural’ or ‘naturally-derived ingredient’;

1 “(B) the listing of each such ingredient is
2 followed by a reference mark; and

3 “(C) the labeling contains the definition of
4 such terms below the ingredient statement; and

5 “(3) the cosmetic is not made using any of the
6 following:

7 “(A) Alkoxylation (including ethoxylation
8 and propoxylation) using ethylene oxide, pro-
9 pylene oxide, or other alkylene oxides.

10 “(B) Deterpenation (other than with
11 steam).

12 “(C) Halogenation as the main reaction.

13 “(D) Ionizing radiation.

14 “(E) Sulphonation as the main reaction.

15 “(F) Treatment with ethylene oxide.

16 “(G) Treatment using mercury.”.

17 (b) DEFINITIONS.—Chapter VI of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-
19 ed by adding at the end the following:

20 **“SEC. 604. DEFINITIONS.**

21 “In this chapter:

22 “(1)(A) The term ‘natural’ means any chemical
23 substance that is naturally occurring and which is—

24 “(i) unprocessed;

1 “(ii) processed only by manual, mechan-
2 ical, naturally derived solvent or gravitational
3 means, by dissolution in water or steam, by flo-
4 tation, or by heating solely to remove water; or

5 “(iii) extracted from air by any means.

6 “(B) Such term does not include petroleum and
7 petroleum derived ingredients.

8 “(2) The term ‘naturally-derived ingredient’
9 means—

10 “(A) any substance where the starting ma-
11 terial is of mineral, plant, microbe, or animal
12 origin but has been chemically processed;

13 “(B) any substance where the starting ma-
14 terial is of mineral, plant, microbe, or animal
15 origin but has been chemically processed and
16 combined with other ingredients, excluding pe-
17 troleum and fossil fuel-derived ingredients; or

18 “(C) an ingredient that is derived from a
19 plant feedstock and bio-manufactured using
20 processes like fermentation, saponification, con-
21 densation, or esterification in order to improve
22 performance or make the ingredient biodegrad-
23 able or sustainable.”.

24 (c) APPLICABILITY.—Section 602(g) of the Federal
25 Food, Drug, and Cosmetic Act, as added by subsection

1 (a), applies beginning on the date that is 2 years after
2 the date of enactment of this Act.

3 **SEC. 3. RECALL AUTHORITY FOR MISBRANDED COSMETICS**
4 **PURPORTING TO BE “NATURAL”.**

5 Chapter VI of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 361 et seq.), as amended by section 2,
7 is further amended by adding at the end the following:

8 **“SEC. 605. RECORDKEEPING, NOTIFICATION, NONDIS-**
9 **TRIBUTION, AND RECALL OF MISBRANDED**
10 **COSMETICS PURPORTING TO BE ‘NATURAL’.**

11 **“(a) RECORDKEEPING.—**A manufacturer or
12 distributor of a cosmetic purporting to be natural within
13 the meaning of section 602(g) shall—

14 **“(1) maintain records—**

15 **“(A) verifying such claim; and**

16 **“(B)(i) demonstrating that each ingredient**
17 **in the cosmetic has been dated by the supplier**
18 **of such ingredient using carbon-14 testing; and**

19 **“(ii) including the results of such testing;**
20 **and**

21 **“(2) make such records available to the Sec-**
22 **retary for inspection, request, or audit.**

23 **“(b) NOTIFICATION OF MISBRANDED COSMETICS.—**

24 **“(1) IN GENERAL.—**A responsible party that
25 has reason to believe that a cosmetic, when intro-

1 duced into or while in interstate commerce, or while
2 held for sale (regardless of whether such sale is the
3 first sale of such cosmetic) after shipment in inter-
4 state commerce, is misbranded under section 602(g)
5 shall notify the Secretary of the identity and location
6 of the cosmetic.

7 “(2) MANNER OF NOTIFICATION.—Notification
8 under paragraph (1) shall be made in such manner
9 and by such means as the Secretary may require by
10 regulation or guidance.

11 “(3) RESPONSIBLE PARTY DEFINED.—For pur-
12 poses of this subsection, the term ‘responsible party’
13 means a brand owner, manufacturer, packager, re-
14 tailer, or distributor of the cosmetic.

15 “(c) VOLUNTARY RECALL.—The Secretary may re-
16 quest that any person who distributes a cosmetic that the
17 Secretary has reason to believe is misbranded under sec-
18 tion 602(g) voluntarily—

19 “(1) recall such cosmetic; and

20 “(2) provide for notice, including to individuals
21 as appropriate, to persons who may be affected by
22 the recall.

23 “(d) ORDER TO CEASE DISTRIBUTION.—

24 “(1) IN GENERAL.—If the Secretary has reason
25 to believe that the cosmetic is misbranded under sec-

1 tion 602(g), the Secretary shall have the authority
2 to issue an order requiring any person who distrib-
3 utes such cosmetic to immediately cease distribution
4 of such cosmetic.

5 “(2) CEASE DISTRIBUTION AND NOTICE.—Any
6 person who is subject to an order under paragraph
7 (1) shall immediately cease distribution of such cos-
8 metic and provide notification as required by such
9 order.

10 “(3) APPEAL.—

11 “(A) 48 HOURS.—A person subject to an
12 order under paragraph (1) may appeal such
13 order to the Secretary within 48 hours of the
14 issuance of such order.

15 “(B) CONTENTS OF APPEAL.—Such appeal
16 may include a request for an informal hearing
17 and a description of any efforts to recall such
18 cosmetic undertaken voluntarily by the person,
19 including after a request under subsection (b).

20 “(C) INFORMAL HEARING.—An informal
21 hearing shall be held as soon as practicable, but
22 not later than 5 calendar days (or less as deter-
23 mined by the Secretary) after such an appeal is
24 filed, unless the parties jointly agree to an ex-
25 tension.

1 “(D) IMPACT ON RECALL.—If an appeal is
2 filed under subparagraph (A), the Secretary
3 may not amend the order to require a recall
4 under subsection (d) until after the conclusion
5 of the hearing under subparagraph (C).

6 “(4) VACATION OF ORDER.—If the Secretary
7 determines that inadequate grounds exist to support
8 the actions required by the order under paragraph
9 (1), the Secretary shall vacate the order.

10 “(e) NOTICE TO CONSUMERS AND HEALTH OFFI-
11 CIALS.—The Secretary shall, as the Secretary determines
12 to be necessary, provide public notice of an order to cease
13 distribution or recalling a misbranded cosmetic under this
14 section to all consumers in a prominent manner on the
15 website of the Food and Drug Administration and to ap-
16 propriate State and local health officials.

17 “(f) SUPPLY CHAIN INFORMATION.—

18 “(1) IN GENERAL.—In the case of a cosmetic
19 that the Secretary has reason to believe is mis-
20 branded under section 602(g), the Secretary shall
21 request that the brand owner named on the label of
22 such cosmetic (as required under section 602(b)(1))
23 submit all of the following information:

24 “(A) The name and place of business of
25 the manufacturer, packager, supplier, or dis-

1 tributor from which such entity received the
2 cosmetic or ingredients for manufacturing such
3 cosmetic.

4 “(B) The name and place of business of
5 any entity (including any retailer) that was pro-
6 vided with such cosmetic by the entity named
7 on the label.

8 “(2) COLLECTION OF ADDITIONAL SUPPLY
9 CHAIN INFORMATION.—In the case of a cosmetic
10 that the Secretary has reason to believe is mis-
11 branded under section 602(g), to the extent nec-
12 essary to protect the safety of the public, the Sec-
13 retary may request that any entity (including a sup-
14 plier of an ingredient, manufacturer, packer, dis-
15 tributor, or retailer) in the supply chain of such cos-
16 metic submit to the Secretary information that is
17 similar to the information described under subpara-
18 graphs (A) and (B) of paragraph (1).

19 “(3) MAINTENANCE OF RECORDS.—Any entity
20 in the supply chain of a cosmetic (including the
21 brand owner named on the label of a cosmetic)
22 shall—

23 “(A) maintain records sufficient to provide
24 the information described in subparagraphs (A)
25 and (B) of paragraph (1); and

1 “(B) provide such information to the Sec-
2 retary upon the request of the Secretary.

3 “(g) SAVINGS CLAUSE.—Nothing contained in this
4 section shall be construed as limiting the authority of the
5 Secretary to issue an order to cease distribution of, or to
6 recall, a cosmetic under any other provision of this Act.”.