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116TH CONGRESS
1ST SESSION

H. R. 5017

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

NOVEMBER 8, 2019

Mr. SEAN PATRICK MALONEY of New York (for himself, Ms. MENG, and Ms. SCHAKOWSKY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Natural Cosmetics Act''.

SEC. 2. COSMETICS WITH CERTAIN TERMS MISBRANDED.

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

"(g) If its packaging or labeling bears the term 'natural' unless—

"(1) if the term 'natural' pertains to the cosmetic overall, the cosmetic contains—

"(A) at least 70 percent natural substances (other than water and salt);

"(B) no fragrance ingredient other than a natural substance or naturally-derived ingredient; and

"(C) other than natural substances and water, contains only naturally-derived ingredients except to the extent a naturally-derived ingredient—

"(i) is not available for a specific function; or

"(ii) is otherwise not feasible;

"(2) if the term 'natural' pertains to one or more ingredients in the cosmetic—

"(A) the ingredient statement identifies natural ingredients individually with the terms 'natural' or 'naturally-derived ingredient';

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

''(C) the labeling contains the definition of such terms below the ingredient statement; and

''(3) the cosmetic is not made using any of the following:

''(A) Alkoxylation (including ethoxylation and propoxylation) using ethylene oxide, propylene oxide, or other alkylene oxides.

''(B) Deterpenation (other than with steam).

''(C) Halogenation as the main reaction.

''(D) Ionizing radiation.

''(E) Sulphonation as the main reaction.

''(F) Treatment with ethylene oxide.

''(G) Treatment using mercury.''.

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

''SEC. 604. DEFINITIONS.

''In this chapter:

''(1)(A) The term 'natural' means any chemical substance that is naturally occurring and which is—

''(i) unprocessed;

''(ii) processed only by manual, mechanical, naturally derived solvent or gravitational means, by dissolution in water or steam, by flotation, or by heating solely to remove water; or

''(iii) extracted from air by any means.

''(B) Such term does not include petroleum and petroleum derived ingredients.

''(2) The term 'naturally-derived ingredient' means—

''(A) any substance where the starting material is of mineral, plant, microbe, or animal origin but has been chemically processed;

''(B) any substance where the starting material is of mineral, plant, microbe, or animal origin but has been chemically processed and combined with other ingredients, excluding petroleum and fossil fuel-derived ingredients; or

''(C) an ingredient that is derived from a plant feedstock and bio-manufactured using processes like fermentation, saponification, condensation, or esterification in order to improve performance or make the ingredient biodegradable or sustainable.''.

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

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

SEC. 3. RECALL AUTHORITY FOR MISBRANDED COSMETICS PURPORTING TO BE "NATURAL".

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

"SEC. 605. RECORDKEEPING, NOTIFICATION, NONDISTRIBUTION, AND RECALL OF MISBRANDED COSMETICS PURPORTING TO BE 'NATURAL'.

''(a) RECORDKEEPING.—A manufacturer or distributer of a cosmetic purporting to be natural within the meaning of section 602(g) shall—

''(1) maintain records—

''(A) verifying such claim; and

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

''(ii) including the results of such testing; and

''(2) make such records available to the Secretary for inspection, request, or audit.

''(b) NOTIFICATION OF MISBRANDED COSMETICS.—

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

duced into or while in interstate commerce, or while held for sale (regardless of whether such sale is the first sale of such cosmetic) after shipment in interstate commerce, is misbranded under section 602(g) shall notify the Secretary of the identity and location of the cosmetic.

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

''(3) RESPONSIBLE PARTY DEFINED.—For purposes of this subsection, the term 'responsible party' means a brand owner, manufacturer, packager, retailer, or distributor of the cosmetic.

''(c) VOLUNTARY RECALL.—The Secretary may request that any person who distributes a cosmetic that the Secretary has reason to believe is misbranded under section 602(g) voluntarily—

''(1) recall such cosmetic; and

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

''(d) ORDER TO CEASE DISTRIBUTION.—

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

tion 602(g), the Secretary shall have the authority to issue an order requiring any person who distributes such cosmetic to immediately cease distribution of such cosmetic.

''(2) CEASE DISTRIBUTION AND NOTICE.—Any person who is subject to an order under paragraph (1) shall immediately cease distribution of such cosmetic and provide notification as required by such order.

''(3) APPEAL.—

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

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

''(C) INFORMAL HEARING.—An informal hearing shall be held as soon as practicable, but not later than 5 calendar days (or less as determined by the Secretary) after such an appeal is filed, unless the parties jointly agree to an extension.

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

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

''(e) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide public notice of an order to cease distribution or recalling a misbranded cosmetic under this section to all consumers in a prominent manner on the website of the Food and Drug Administration and to appropriate State and local health officials.

''(f) SUPPLY CHAIN INFORMATION.—

''(1) IN GENERAL.—In the case of a cosmetic that the Secretary has reason to believe is misbranded under section 602(g), the Secretary shall request that the brand owner named on the label of such cosmetic (as required under section 602(b)(1)) submit all of the following information:

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

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

''(B) The name and place of business of any entity (including any retailer) that was provided with such cosmetic by the entity named on the label.

''(2) COLLECTION OF ADDITIONAL SUPPLY CHAIN INFORMATION.—In the case of a cosmetic that the Secretary has reason to believe is misbranded under section 602(g), to the extent necessary to protect the safety of the public, the Secretary may request that any entity (including a supplier of an ingredient, manufacturer, packer, distributor, or retailer) in the supply chain of such cosmetic submit to the Secretary information that is similar to the information described under subparagraphs (A) and (B) of paragraph (1).

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

''(A) maintain records sufficient to provide the information described in subparagraphs (A) and (B) of paragraph (1); and

''(B) provide such information to the Secretary upon the request of the Secretary.

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

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