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117TH CONGRESS
1ST SESSION

H. R. 5538

To amend title VI of the Federal Food, Drug, and Cosmetic Act to provide for greater transparency with respect to fragrance and flavor ingredients in cosmetics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2021

Ms. SCHAKOWSKY (for herself and Ms. MATSUI) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title VI of the Federal Food, Drug, and Cosmetic Act to provide for greater transparency with respect to fragrance and flavor ingredients in cosmetics, 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 ''Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021''.

SEC. 2. COSMETIC REGULATION.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amended—

(1) by inserting before section 601 the following:

"Subchapter A—Adulterated and Misbranded Cosmetics";

(2) in section 602, by adding at the end the following:

''(g) If the ingredient information required to be disclosed pursuant to section 611 is not disclosed in accordance with such section.

''(h) If it contains ingredients specified in a list included in section 612 and its packaging or labeling fails to include any such ingredient.''; and

(3) by adding at the end the following:

"Subchapter B—Fragrances and Flavors

"SEC. 611. WEBSITE LABELING OF FRAGRANCE AND FLAVOR INGREDIENTS.

''(a) IN GENERAL.—Effective beginning on the date that is one year after the date of the enactment of the Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021, a brand owner shall disclose in an electronically readable format on the website of the brand owner, and make available to any relevant internet vendor, with respect to each cosmetic sold or offered for sale in interstate commerce by such brand owner, the following information:

''(1) any fragrance or flavor ingredient present in such cosmetic at a concentration that equals or exceeds .01 percent;

''(2) any fragrance or flavor ingredient present in such cosmetic included on a list specified in section 612(b);

''(3) any fragrance allergen in such cosmetic if the fragrance allergen meets the criteria specified in section 612(c);

''(4) the functional purpose served by each such fragrance or flavor ingredient;

''(5) a link to the URL of the list referred to in paragraph (2) on which the fragrance or flavor ingredient present in such cosmetic appears (including a cosmetic intended for retail consumer sale or professional use); and

''(6) a link to the hazard communication safety data sheet for any such cosmetic intended for professional use.

''(b) UPDATES.—In the case of an update to any of the lists specified in subsection (b) or (c) of section 612 with respect to a cosmetic sold or offered for sale in interstate commerce by a brand owner, the brand owner shall revise the disclosure made under subsection (a) to reflect such update not later than seven months after the date

on which such update is formally noticed by the authoritative body who administers the list.

"SEC. 612. COSMETIC INGREDIENT LABEL DISCLOSURE.

"(a) IN GENERAL.—Effective beginning on the date that is 2 years after the date of the enactment of the Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021, for purposes of section 602(h), in the case of a cosmetic in which any of the ingredients specified in subsection (b) or fragrance allergens specified in subsection (c) is present, the packaging or labeling of such cosmetic shall—

"(1) list each such ingredient; and

"(2) not later than 18 months after the date on which an update to any of the lists referred to in subsection (b) or (c) with respect to an ingredient or allergen present in such cosmetic are formally noticed by the authoritative body who administers the list, include any necessary revisions with respect to such ingredient or fragrance allergen to reflect such update.

"(b) INGREDIENTS SPECIFIED.—The ingredients specified in this subsection are the following chemicals (including chemicals included in any list specified in this subsection after the date of the enactment of this subchapter):

''(1) Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the Environmental Protection Agency's Integrated Risk Information System.

''(2) Chemicals that are identified as carcinogenic to humans, likely to be carcinogenic to humans, or as group A, B1, or B2 carcinogens, in the Environmental Protection Agency's Integrated Risk Information System.

''(3) Persistent, bioaccumulative, and toxic Priority Chemicals identified by the Environmental Protection Agency's National Waste Minimization Program as of February 22, 2016.

''(4) Chemicals that are identified in volumes 1 through 4 of the Reports on Human Exposure to Environmental Chemicals issued by the Centers for Disease Control and Prevention (and any updates to such reports).

''(5) Toxic pollutants listed under section 307(a)(1) of the Federal Water Pollution Control Act and priority pollutants identified in appendix A to part 423 of title 40, Code of Federal Regulations (or successor regulations).

''(6) Chemicals classified as 'Persistent, Bioaccumulative and Toxic' by the Toxics Release In-

ventory published by the Environmental Protection Agency pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act of 1986.

''(7) Chemicals that are identified in the Agency for Toxic Substances and Disease Registry's Toxic Substances Portal.

''(8) Chemicals that are hazardous substances, as such term is defined in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.

''(9) Reproductive and developmental toxicants identified by monographs issued by the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction.

''(10) Chemicals that are identified as known to be, or reasonably anticipated to be human carcinogens by the most recent Report on Carcinogens prepared by the National Toxicology Program pursuant to section 301(b)(4) of the Public Health Service Act.

''(11) Chemicals identified as persistent, bioaccumulative, and toxic (PBT) chemicals by the Department of Ecology of the State of Washington (WAC 173–333 (2006)).

''(12) Chemicals specified in Chapter 6.6 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 (sections 25249.5 through 25249.14 of the California Health and Safety Code), List of Reproductive and Developmental Toxicants and Carcinogens.

''(13) Chemicals for which primary maximum contaminant levels have been established and adopted under sections 64431, 64444, or 64444.5 of division 22 of title 26 of the California Code of Regulations and chemicals for which notification levels, as defined in section 116455 of the California Health and Safety Code, have been established by the California State Water Resources Control Board.

''(14) Chemicals identified as toxic air contaminants under section 93000 or 93001 of title 17 of the California Code of Regulations.

''(15) Substances classified as carcinogens, mutagens or reproductive toxicants in Appendices 1 through 6 of Annex XVII to Regulation (EC) No. 1907/2006 of the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) law, as revised by the Commission Regulation (EU) 2020/2096 of 15 December 2020.

''(16) Chemicals included in the European Union Candidate List of Substances of Very High Concern in accordance with Article 59 of the REACH Regulation (EC) No. 1907/2006 on the basis of fulfilling the criteria defined in Article 57(f) for endocrine disrupting properties.

''(17) Chemicals included in such European Chemicals Agency Candidate List of Substances of Very High Concern on the basis of fulfilling the criteria defined in Article 57(d), Article 57(e), or Article 57(f) for persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, properties.

''(18) Chemicals classified by the European Union in Annex VI to Regulation (EC) No. 1272/2008 as respiratory sensitizer category 1.

''(19) Chemicals that are identified as persistent, bioaccumulative, and inherently toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List pursuant to subsection 66(1) of the Canadian Environmental Protection Act, 1999.

''(20) Group 1, 2A, or 2B carcinogens identified by the International Agency for Research on Cancer of the World Health Organization.

''(21) Chemicals that are identified on Part A of the list of Chemicals for Priority Action prepared by the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic.

''(c) FRAGRANCE ALLERGENS.—A fragrance allergen specified in this subsection is an allergen that is—

''(1) included in Annex III of European Union Cosmetics Regulation No. 1223/2009, as required to be disclosed pursuant to European Union Detergents Regulation No. 21648/2004 (including any subsequent updates to those regulations); and

''(2) present in—

''(A) a rinse-off cosmetic at a concentration at or above 0.01 percent; or

''(B) a leave-on cosmetic product at a concentration at or above 0.001 percent.

''(d) MASTER LIST.—

''(1) IN GENERAL.—Not later than 6 months after the date of the enactment of the Cosmetic Fragrance and Flavor Ingredient Right to Know Act of 2021, the Secretary shall—

''(A) establish a master list of the chemicals that appear on the lists specified in subsections (b) and (c);

"(B) post such master list on a publicly available website of the Food and Drug Administration; and

"(C) establish a voluntary electronic distribution list to which cosmetic manufacturers and other interested parties may subscribe to receive a copy of the master list and any subsequent updates.

"(2) UPDATES.—

"(A) IN GENERAL.—The Secretary shall maintain the master list established under paragraph (1) and make updates to such list as necessary.

"(B) NOTIFICATION.—Not later than 30 days after making an update pursuant to subparagraph (A), the Secretary shall notify subscribers to the electronic distribution list referred to in paragraph (1)(C) of that update.

"(C) SEMI-ANNUAL UPDATES.—Not less frequently than twice per year, the Secretary shall publish on a publicly available website of the Food and Drug Administration a list of updates to the master list made during the preceding 6-month period that includes summaries

of any chemicals added to or removed from the lists specified in subsections (b) and (c).

"SEC. 613. GENERAL PROVISIONS.

"(a) TREATMENT OF CONFIDENTIAL COMMERCIAL INFORMATION AND TRADE SECRETS.—Notwithstanding any other provision of law, for purposes of applying section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code—

"(1) an ingredient required to be listed on a cosmetic packaging or labeling or on the website of a brand owner (or other entity) under this section shall not be treated as a trade secret; and

"(2) the concentration of any such ingredient shall be treated as confidential commercial information.

"(b) DEFINITIONS.—In this subchapter:

"(1) BRAND OWNER.—The term 'brand owner' means the entity responsible for bringing a cosmetic to market for retail consumer sale or professional use.

"(2) ELECTRONICALLY READABLE FORMAT.—The term 'electronically readable format' means, with respect to information, that the information provided is—

"(A) is machine readable by automated systems, including, web browsers, accessibility software to aid the disabled, automated scripts, and other software programs or applications;

"(B) is not restricted from access by search engines;

"(C) is not restricted from access by a requirement for registration, the provision of personally identifiable information, or the use of CAPTCHA or similar challenge response test technologies, whether visual, auditory, or otherwise; and

"(D) conforms to the most current version of the Web Content Accessibility Guidelines adopted by the Web Content Accessibility Guidelines Working Group of the World Wide Web Consortium.

"(3) FLAVOR INGREDIENT.—The term 'flavor ingredient' means, with respect to a cosmetic, any intentionally added substance or complex mixture of aroma chemicals, flavor chemicals, natural essential oils, and other functional ingredient or ingredients, including the constituent ingredients of botanicals, for which the purpose is to impart a flavor or taste, or to counteract a flavor or taste.

''(4) FRAGRANCE INGREDIENT.—The term 'fragrance ingredient' means, with respect to a cosmetic, any intentionally added substance or complex mixture of aroma chemicals, natural essential oils, and other functional ingredient or ingredients for which the purpose is to impart an odor or scent, or to counteract an odor.

''(5) INGREDIENT.—The term 'ingredient' means a chemical in a cosmetic, including—

''(A) a chemical that has a technical or functional effect in the cosmetic, including the breakdown products of an intentionally added chemical that also have a functional or technical effect in the cosmetic;

''(B) a substance that is present by reason of having been added to a cosmetic during processing for the substance's technical or functional effect;

''(C) a fragrance, flavor, preservative, or colorant (and the components thereof); and

''(D) any individual component that the Secretary deems to be an ingredient for purposes of this subchapter.

''(6) PROFESSIONAL USE.—The term 'professional use' means—

"(A) the application of a cosmetic to a human customer or client that is intended only for use by an employee or contractor, in settings such as cosmetology, nail care, barbering, esthetics, spa, and other professions as determined by the Secretary through regulation; or

"(B) the use by, or application to, a human of a cosmetic purchased from a hair salon, nail salon, beauty salon, spa, or other establishment that provides cosmetic treatment services for humans.".

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