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117TH CONGRESS
1ST SESSION

H. R. 5539

To amend title VI of the Federal Food, Drug, and Cosmetic Act to ensure the supply chain transparency needed for companies to make safe cosmetics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 2021

Ms. SCHAKOWSKY 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 ensure the supply chain transparency needed for companies to make safe 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 Supply Chain Transparency 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";

and

(2) by adding at the end the following:

"Subchapter B—Supply Chain Transparency

"SEC. 611. DEFINITIONS.

''In this subchapter:

''(1) BRAND OWNER.—The term 'brand owner' means the entity responsible for bringing a cosmetic to market.

''(2) FLAVOR OR FRAGRANCE COMPANY.—The term 'flavor or fragrance company' means an entity that makes or supplies fragrance or flavor ingredients or fragrance or flavor formulations.

''(3) FORMULATING LABORATORY.—The term 'formulating laboratory' means an entity that supplies a finished cosmetic product to a retailer or cosmetic company to sell under the retailer or cosmetic company's brand name.

''(4) HARMFUL TO HUMAN HEALTH OR THE ENVIRONMENT.—The phrase 'harmful to human health or the environment' means, with respect to a nonfunctional constituent—

"(A) being—

"(i) a reproductive or developmental toxicant;

"(ii) persistent, bioaccumulative, and toxic;

"(iii) an allergen; or

"(iv) an endocrine disruptor, carcinogen, or mutagen; and

"(B) present on the most recent version in effect of any of the following lists:

"(i) 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.

"(ii) Chemicals classified as 'Persistent, Bioaccumulative and Toxic' by the Toxics Release Inventory published by the Environmental Protection Agency pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act of 1986.

"(iii) European Union Regulation 1223/2009/EC on Cosmetic Products, as amended by Regulation (EU) 2020/1683, Annex II–Prohibited Substances.

"(iv) Annex III of European Union Cosmetics Regulation No. 1223/2009, as required to be disclosed pursuant to European Union Detergents Regulation No. 21648/2004.

"(v) 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.

"(vi) Substances classified as carcinogens, mutagens, or reproductive toxicants in Appendices 1–6 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 December 15, 2020.

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

''(viii) Any other list the Secretary determines appropriate for purposes of this subchapter.

''(5) INGREDIENT.—The term 'ingredient' means an intentionally added chemical in a cosmetic that has a technical or functional effect, including—

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

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

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

''(6) INCIDENTAL COMPONENT.—The term 'incidental component' means—

''(A) a chemical added during the manufacturing process at any point in a cosmetic's, or an ingredient's, supply chain, but which has no functional or technical effect in the finished cosmetic; or

"(B) a chemical present in the environment which was introduced into a cosmetic, or into an ingredient, at any point in the supply chain for the cosmetic or ingredient.

"(7) MANUFACTURER.—The term 'manufacturer' means any entity that—

"(A) produces an ingredient; or

"(B) combines one or more ingredients to produce a cosmetic.

"(8) NONFUNCTIONAL CONSTITUENT.—The term 'nonfunctional constituent' means a chemical that has no functional or technical effect on the product or ingredient and is present—

"(A) as an incidental component of an intentionally added ingredient;

"(B) as a breakdown product of an intentionally added ingredient;

"(C) as a byproduct of the manufacturing process;

"(D) due to storage of primary substances; or

"(E) due to instability of the packaging.

"(9) RAW MATERIAL.—The term 'raw material' means a substance or mixture of substances that—

''(A) is used in the manufacture of a cosmetic for commercial distribution; and

''(B) is supplied to a cosmetic manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.

''(10) SUPPLIER.—The term 'supplier'—

''(A) means an entity that supplies a cosmetic, cosmetic packaging, or an ingredient or raw material of a cosmetic or cosmetic packaging; and

''(B) includes any such entity that is a manufacturer, a formulating laboratory, or a fragrance or flavor company.

''SEC. 612. COSMETIC AND INGREDIENT SAFETY INFORMATION.

''At the request of a brand owner of a cosmetic, a supplier of the cosmetic or any ingredient therein shall, not later than 90 days after receipt of such request, provide to the brand owner, with respect to the cosmetic or ingredient, any of the following information:

''(1)(A) Functions and uses.

''(B) The human health and environmental hazards.

''(C) The physical and chemical properties.

''(D) The Chemical Abstracts Services Registry number of any such ingredient.

''(E) Environmental exposure and fate information.

''(F) Any other information used to substantiate the safety of such ingredient.

''(2) A full and complete listing of ingredients in fragrance or flavor formulations, preservative systems, or other ingredient formulations, including the presence of any allergens.

''(3) A full and complete listing of ingredients in a finished cosmetic presented in descending order of predominance by weight, except that ingredients present in amounts of 1 percent or less by weight can be placed in any order at the end of the ingredient statement.

''(4) A certificate of analysis for the ingredient.

''SEC. 613. PROCESS FOR ESTABLISHING AN FDA LIST OF NONFUNCTIONAL CONSTITUENTS KNOWN OR REASONABLY EXPECTED TO BE PRESENT IN COSMETICS AND INGREDIENTS.

''(a) IN GENERAL.—The Secretary shall create and maintain a list of nonfunctional constituents to guide testing under this subchapter conducted by suppliers of cosmetics and ingredients.

''(b) CONTENTS.—The list under subsection (a) shall consist of nonfunctional constituents that are—

''(1) known or reasonably expected to be present in cosmetics or ingredients; and

''(2) subject to subsection (e)(2), harmful to human health or the environment.

''(c) IDENTIFICATION OF INGREDIENTS AND COSMETICS.—For each nonfunctional constituent on the list under subsection (a), the Secretary shall identify the specific ingredient or cosmetic, or category of ingredients or cosmetics, in which the nonfunctional constituent is known or reasonably expected to be present.

''(d) INITIAL LIST.—

''(1) IN GENERAL.—In creating the initial list under subsection (a), the Secretary shall—

''(A) publish a proposed list and provide an opportunity for public comment on such proposed list for a period of 60 days; and

''(B) not later than 18 months after the date of enactment of the Cosmetic Supply Chain Transparency Act of 2021, finalize and publish the list.

''(2) ADVISORY COMMITTEE.—

''(A) IN GENERAL.—Not later than 9 months after the date of enactment of the Cos-

metic Supply Chain Transparency Act of 2021, the Secretary shall convene an advisory committee to advise the Secretary on—

"(i) creating the initial list under subsection (a); and

"(ii) best practices related to analytical testing for nonfunctional constituents in cosmetics and ingredients.

"(B) MEMBERSHIP.—The membership of the advisory committee convened under subparagraph (A) shall consist of an equal number of—

"(i) representatives from industry;

"(ii) representatives from the nonprofit community;

"(iii) representatives from the scientific community; and

"(iv) representatives from the medical and public health community.

"(C) TERMINATION.—The Secretary shall terminate the advisory committee convened under this paragraph upon the finalization of the initial list pursuant to paragraph (1).

"(e) UPDATES.—Not less than annually after the finalization pursuant to subsection (d) of the initial list

under subsection (a), and not less than annually thereafter, the Secretary shall—

"(1) review the list under subsection (a);

"(2) after providing a period of at least 30 days for public comment, update the list by adding nonfunctional constituents that are known or reasonably expected to be present in a cosmetic or ingredient as specified in subsection (b)(1) and—

"(A) are determined by the Secretary to meet the standard specified in section 611(4)(A) based on existing and emerging science; or

"(B) have been added to one of the lists in section 611(4)(B); and

"(3) update the list by adding any nonfunctional constituent whose addition was approved pursuant to a petition under subsection (f).

"(f) PETITION PROCESS FOR ADDING NONFUNCTIONAL CONSTITUENTS OR NEW LISTS.—

"(1) IN GENERAL.—Any person may petition, in accordance with paragraph (3), to add—

"(A) a nonfunctional constituent to the list under subsection (a); or

"(B) a new list to the lists specified in section 611(4)(B).

''(2) DEVELOPMENT OF PROCESS.—The Secretary—

''(A) not later than 24 months after the date of enactment of the Cosmetic Supply Chain Transparency Act of 2021, shall develop and publish the process for submitting a petition under this subsection; and

''(B) may periodically review and update such process.

''(3) REQUIREMENTS FOR PROCESS.—The process developed and updated by the Secretary under paragraph (2) shall be consistent with the following:

''(A) Such process shall specify the necessary scientific justification that must be included in a petition.

''(B) The Secretary shall—

''(i) provide a 30-day period for public comment on a petition; and

''(ii) not later than 90 days after the close of such public comment period, approve or deny the petition.

''(C) If the Secretary approves a petition, the Secretary shall provide notice in the Federal Register of each addition made pursuant to such approval.

''(D) In denying a petition, the Secretary shall provide a written justification to the petitioner for the denial.

''(g) GUIDANCE.—The Secretary—

''(1) shall, concurrently with the publication of the initial list under subsection (a), and upon adding any nonfunctional constituent pursuant to subsection (e) or (f) to the list under subsection (a), issue guidance for industry on best practices related to—

''(A) analytical testing for nonfunctional constituents in cosmetics and ingredients; and

''(B) detection limits; and

''(2) may periodically review and update such guidance.

''SEC. 614. TREATMENT OF NONFUNCTIONAL CONSTITUENTS.

''A supplier of an ingredient or cosmetic shall—

''(1) not later than 1 year after a nonfunctional constituent is added to the list under section 613(a) pursuant to subsection (d), (e), or (f) of section 613, conduct testing for such nonfunctional constituent; and

''(2) prior to the sale of the ingredient or cosmetic to the brand owner, provide the brand owner a certificate of analysis that includes—

''(A) the levels of each such nonfunctional constituent present;

''(B) any analytical test used; and

''(C) the detection limits of any analytical test used to detect each such nonfunctional constituent.

''SEC. 615. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED COSMETICS.

''(a) SUPPLY CHAIN INFORMATION.—In the case of a cosmetic that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of this Act, the Secretary shall request that the brand owner named on the label of such cosmetic submit to the Secretary all of the following information:

''(1) The name and place of business of the manufacturer of the cosmetic and any supplier of an ingredient or raw material used in the manufacture of the cosmetic.

''(2) The name and place of business of any entity (including any retailer) to which the brand owner provided the cosmetic.

''(b) COLLECTION OF ADDITIONAL SUPPLY CHAIN INFORMATION.—In the case of a cosmetic that the Secretary has reason to believe is adulterated, misbranded,

or otherwise in violation of this Act, to the extent necessary to protect the safety of the public, the Secretary may request that any entity in the supply chain of such cosmetic submit to the Secretary information that is similar to the information described in paragraphs (1) and (2) of subsection (a).

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

''(1) maintain records sufficient to provide the information described in paragraphs (1) and (2) of subsection (a); and

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

''SEC. 616. CIVIL PENALTIES.

''Any person that violates section 612, 614, or 615 shall be liable to the United States for a civil penalty in an amount not to exceed $1,500 for each day on which such violation continues.''.

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