AMENDMENT

OFFERED BY M__. _____

[Page/line numbers refer to OTCMONOGRAPH__05, dated January 12, 2018]

On page 56, after line 8, insert the following:

SEC. 105. REGISTRATION OF COSMETICS FACILITIES AND COSMETIC INGREDIENT STATEMENTS.

(a) AMENDMENTS.—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) COSMETIC FORMULATION.—The term 'cosmetic formulation' means a preparation of cosmetic raw materials with a qualitatively and quantitatively set composition.

''(2) COSMETIC PRODUCT.—The term 'cosmetic product' means a cosmetic comprised of a specified set of ingredients, which may come in a range of possible amounts for each ingredient and which may include a variety of fragrances and colors, and in some specific cosmetic applications, flavors.

''(3) FACILITY.—The term 'facility' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds cosmetic products or cosmetic formulations, or any other entity whose name and address appear on the label of a cosmetic product. Such term does not include—

''(A) beauty shops and salons that do not otherwise manufacture, process, or package cosmetics at that location;

''(B) cosmetic product retailers, including individual sales representatives, retail distribution facilities, retail warehouses, and pharmacies, that do not otherwise manufacture, process, or package cosmetics at that location;

''(C) hospitals, physicians' offices, and health care clinics;

''(D) public health agencies and other nonprofit entities that provide cosmetics directly to the consumer;

''(E) hotels and other entities that provide complimentary cosmetics to guests;

''(F) trade shows and other venues where cosmetic product samples are provided free of charge;

''(G) domestic manufacturers with less than $100,000 in gross annual sales of cosmetic products, except for any manufacturer that is engaged in the manufacturing, processing, or distributing of products intended to be injected under the skin or into the eye, including tattoo ink;

''(H) entities that manufacture or compound cosmetic products solely for use in research, teaching, or pilot plant production and not for sale.

''(4) FOREIGN FACILITY.—The term 'foreign facility' means a facility that manufactures, processes, packs, or holds, a cosmetic formulation or cosmetic product that is exported to the United States without further processing or packaging inside the United States. A cosmetic is not considered to have undergone further processing or packaging for purposes of this definition solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the cosmetic.

''(5) NONFUNCTIONAL CONSTITUENT.—The term 'nonfunctional constituent' means any substance that is an incidental component of an ingredient, a breakdown product of an ingredient or a by-product of the manufacturing process that has not been intentionally added as a separate substance and serves no technical function in the cosmetic.

''(6) RESPONSIBLE PERSON.—The term 'responsible person' means—

''(A) the brand owner, operator, or agent in charge who is the domestic or foreign manufacturer, processor, or entity whose name appears on the label of a cosmetic product or a cosmetic formulation distributed in the United States, except for entities described in subparagraphs (A) through (H) of paragraph (3); or

''(B) a contract manufacturer who provides cosmetic products to the entities described in subparagraphs (A) through (H) of paragraph (3).

''SEC. 605. REGISTRATION OF COSMETIC FACILITIES.

''(a) REGISTRATION AND FEES FOR EXISTING MANUFACTURING OR PROCESSING OF COSMETICS.—

''(1) REGISTRATION, IN GENERAL.—Each responsible person engaged in manufacturing, or proc-

essing, or whose name appears on the label of a cosmetic product or a cosmetic formulation distributed in the United States shall register all of the responsible person's facilities with the Food and Drug Administration. A responsible person required to register under this subsection shall, not later than 90 days after the Secretary announces the establishment of an electronic registration system for purposes of this section, submit a registration utilizing such system which shall be effective for fiscal year 2018.

''(2) FEES.—If the average gross annual sales in the United States of cosmetic products of all of the responsible person's facilities registered under paragraph (1) for the previous 3-year period is greater than $500,000, a registration shall not be complete under this subsection until the responsible person has paid any registration fee required.

''(b) REGISTRATION FOR EXISTING PACKING OR HOLDING FACILITIES.—Each facility engaged in packing or holding a cosmetic product distributed in the United States shall register with the Food and Drug Administration. Each facility required to register under this subsection shall, not later than 90 days after the Secretary announces the establishment of an electronic registration

system for purposes of this section, submit a registration utilizing such system which shall be effective for fiscal year 2018.

''(c) REGISTRATION BY NEW FACILITIES.—A responsible person first engaging after the date of enactment of the Cosmetic Safety Enhancement Act of 2018 in an activity that would require it to register under subsection (a) or (b) shall register with the Food and Drug Administration immediately upon engaging in such activity, and thereafter in accordance with subsection (a) or (b).

''(d) CHANGES TO INFORMATION.—A responsible person that submitted a registration under this section shall notify the Food and Drug Administration of any change to the information required under subsection (a) or (b) not later than 30 days after the date of such change, unless otherwise specified by the Food and Drug Administration.

''(e) ANNUAL REGISTRATION RENEWAL.—A responsible person that continues to engage in any activity that would require registration under subsection (a) or (b) shall submit to the Secretary an annual registration during the first quarter of the fiscal year for which such renewed registration shall be effective.

''(f) FORMAT; CONTENTS.—

''(1) ELECTRONIC FORMAT.—Each registration shall be submitted using an electronic format, as specified in a registration form provided by the Food and Drug Administration.

''(2) CONTENTS.—The registration shall contain the following information:

''(A) Each facility's name and full address, identifying the precise physical location of the facility.

''(B) The identity of the facility, including the unique facility identifier, if any, previously assigned by the Food and Drug Administration to the facility under subsection (g).

''(C) All business trading names used by the facility.

''(D) The product category or categories of each cosmetic product or cosmetic formulation manufactured, processed, packed, or held at the facility or on whose label the facility's name and address appear.

''(E) The type or types of activities conducted at the facility (such as manufacturing, processing, packing, or holding).

''(F) The name, title, street address, telephone number, and electronic contact information of the emergency contact for the facility.

''(G) In the case of a foreign facility, the name, street address, telephone number, emergency contact information for the facility, the name of the United States agent for the facility, and the phone number and electronic contact information of the United States agent.

''(H) The name, title, street address, telephone number, and electronic contact information of the individual submitting the registration.

''(I) An assurance that the Food and Drug Administration will be permitted to inspect such facility at the times and in the manner permitted by this Act.

''(J) Additional information pertaining to the facility or to the cosmetic products or cosmetic formulations manufactured, processed, packed, or held at the facility, or on whose label the facility's name and address appear, including all brand names known to consumers, as the Food and Drug Administration may require by regulation.

''(3) ABBREVIATED REGISTRATION.—The Food and Drug Administration shall provide for an abbreviated registration renewal process for any facility that has not had any changes to such information with respect to the facility or facilities involved since the facility submitted the preceding registration.

''(g) INCOMPLETE OR INACCURATE REGISTRATION.—

''(1) IN GENERAL.—Not earlier than 10 days after providing notice of the intent to cancel a registration and the basis for such cancellation, the Food and Drug Administration may cancel a registration under this section if the Food and Drug Administration has reasonable grounds to believe that the registration was not properly completed or updated in accordance with this section, if a required registration fee has not been paid within 30 days, or if the registration otherwise contains false, incomplete, or inaccurate information.

''(2) TIMELY UPDATE OR CORRECTION.—If, not later than 7 days after receipt of a notice of intent to cancel, the facility corrects the registration in accordance with the basis for the cancellation, and the required registration fee, if any, is paid, the Food

and Drug Administration shall not cancel such registration.

''(h) UNIQUE IDENTIFIER.—At the time of the initial registration of any cosmetic facility under this section, the Food and Drug Administration shall assign a unique identifier to the facility.

''(i) REGISTRY OF FACILITIES.—

''(1) IN GENERAL.—The Food and Drug Administration shall compile, maintain, and update a registry of facilities that are registered under this section, and shall remove from such registry the name of any facility whose registration under this section is cancelled. The registry shall be publicly available.

''(2) PUBLIC AVAILABILITY EXCEPTIONS.—Information derived from the registry or registration documents that discloses the residential address of a responsible person, facility, or that discloses specific facilities where specific cosmetic products are manufactured or processed shall not be subject to disclosure under section 552 of title 5, United States Code.

''SEC. 606. COSMETIC INGREDIENT STATEMENTS.

''(a) IN GENERAL.—For each cosmetic product, the responsible person shall submit to the Food and Drug Ad-

ministration a cosmetic ingredient statement, at such time and in such manner as the Food and Drug Administration may prescribe. The cosmetic ingredient statement shall not become effective until the responsible person pays any applicable fee required.

''(b) SUBMISSION OF A COSMETIC INGREDIENT STATEMENT.—

''(1) EXISTING COSMETIC PRODUCTS.—In the case of a cosmetic product that is marketed on the date of enactment of the Cosmetic Safety Enhancement Act of 2018, the responsible person shall submit a cosmetic ingredient statement not later than July 30, 2018. The responsible person shall submit to the Food and Drug Administration an annual renewal of such statement during the first quarter of the fiscal year for which such renewed statement is applicable.

''(2) COSMETIC INGREDIENT STATEMENT FOR NEW COSMETIC PRODUCTS.—

''(A) IN GENERAL.—Except as provided under subparagraph (B), in the case of a cosmetic product that is first marketed after the date of enactment of the Cosmetic Safety Enhancement Act of 2018 or a cosmetic product that is reformulated after such date of enact-

ment, the responsible person shall submit a cosmetic ingredient statement to the Food and Drug Administration prior to first marketing the new cosmetic product or the reformulated cosmetic product, and annually thereafter during the first quarter of the fiscal year for which the cosmetic ingredient statement is applicable.

''(B) SMALL BUSINESSES.—The Food and Drug Administration shall allow a responsible person that is a business that meets the applicable industry-based small business size standard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have an additional time period, as determined by the Secretary, to submit an initial new cosmetic ingredient statement under subparagraph (A). Such responsible person shall submit a cosmetic ingredient statement annually thereafter during the first quarter of the fiscal year.

''(C) DEFINITION.—A cosmetic product shall not be considered first marketed or reformulated after the date of enactment under subparagraph (A) if the only change in such product is in—

''(i) the amount of an existing ingredient if it is within the range previously reported under subsection (c)(2)(E); or

''(ii) the addition or subtraction of a fragrance, flavor, or color, or such other interchangeable ingredients specified by the Food and Drug Administration in regulations or guidance, previously reported as a potential ingredient under subsection (c)(2)(E), if, in the case of such an addition, the amount is within the range previously reported.

''(c) FORMAT; CONTENTS.—

''(1) FORM.—For each cosmetic product, the cosmetic ingredient statement shall be submitted using an electronic format, as specified in a cosmetic and ingredient form provided by the Food and Drug Administration.

''(2) CONTENTS.—The cosmetic ingredient statement shall include the following information:

''(A) The unique identifier, assigned under section 605(g), as applicable, of—

''(i) the facility or facilities where the cosmetic product is manufactured, processed, packed, or held or, if the same cos-

metic product is manufactured, processed, packed, or held in more than one facility, the unique facility identifier of each facility where it is manufactured, processed, packed, or held; and

''(ii) the facility whose name and address appear on the label, unless the statement is filed by a contract manufacturer, described in section 604(6)(B).

''(B) The brand name and the full name for the cosmetic product as it appears on the label.

''(C) The cosmetic product listing number, if any, previously assigned by the Food and Drug Administration under subsection (f) to the cosmetic product.

''(D) The applicable cosmetic category for the cosmetic product.

''(E) A list of ingredients in the cosmetic product, including a range of possible amounts of each ingredient, and with each ingredient identified by the name adopted in regulations promulgated by the Food and Drug Administration, if any, or by the common or usual

name of the ingredient. The cosmetic ingredient statement shall contain—

''(i) a list of fragrances, flavors, and colors that may be included in the product, interchangeably, with ranges of possible amounts, which shall include—

''(I) in the case of fragrances that are purchased from a fragrance supplier, the fragrances shall be identified by the name or code provided by the supplier, and include the name and contact information for the fragrance supplier;

''(II) in the case of flavors that are purchased from a flavor supplier, the flavors shall be identified by the name or code provided by the supplier, and include the name and contact information for the flavor supplier; and

''(III) if requested by the Food and Drug Administration by means of a written notification to the fragrance or flavor supplier, the complete list of ingredients in specific fragrances or

flavors (and the supplier shall have 30 days to provide such list to the Food and Drug Administration); and

''(ii) other appropriate interchangeable ingredients as the Food and Drug Administration may specify in regulations or guidance that may be included in the product, with ranges of possible amounts.

''(F) The title and full contact information of each individual submitting the statement.

''(G) Such additional information pertaining to the cosmetic product as the Food and Drug Administration may require.

''(3) COSMETIC INGREDIENT STATEMENT FOR CERTAIN SMALL BUSINESSES.—

''(A) IN GENERAL.—Notwithstanding any other provision of this subsection, the Food and Drug Administration may permit a simplified cosmetic ingredient statement under this section for a responsible person that—

''(i) is a business that meets the applicable industry-based small business size standard established by the Administrator of the Small Business Administration

under section 3 of the Small Business Act; and

''(ii) has had an average of less than $500,000 in annual domestic cosmetic sales over the previous 3 years.

''(B) CONTENTS.—A responsible person described in subparagraph (A) shall include in each cosmetic ingredient statement under this section, at a minimum, a list of ingredients in the cosmetic product and the applicable cosmetic category for the cosmetic product. If a cosmetic product includes a fragrance or flavor purchased from a fragrance or flavor supplier, the responsible person must, at a minimum, include a list of all fragrances and flavors contained in the cosmetic product and contact information for the fragrance or flavor supplier, including the supplier's name, street address, telephone number, and electronic contact information. In the case of a written notification under paragraph (2)(E)(i)(III) provided by the Food and Drug Administration to the responsible person for the cosmetic manufacturer, the Food and Drug Administration may request, from the fragrance or flavor supplier, the com-

plete list of ingredients in specific fragrances or flavors, and the supplier shall have 30 days to provide such list to the Food and Drug Administration.

''(d) INCOMPLETE OR INACCURATE COSMETIC INGREDIENT STATEMENT.—

''(1) IN GENERAL.—Not earlier than 10 days after providing notice under paragraph (2), the Food and Drug Administration may nullify a cosmetic ingredient statement filed under this section if the Food and Drug Administration has reasonable grounds to believe that the cosmetic ingredient statement was not completed or updated in accordance with this section or otherwise contains false, incomplete, or inaccurate information.

''(2) NOTICE OF NULLIFICATION.—A nullification under paragraph (1) shall be preceded by notice to the responsible person of the intent to cancel the cosmetic ingredient statement and the basis for such cancellation.

''(3) TIMELY UPDATE OR CORRECTION.—If the cosmetic ingredient statement is appropriately updated or corrected not later than 7 days after notice is provided under paragraph (1), the Food and Drug

Administration shall not nullify such cosmetic ingredient statement.

''(4) EFFECT OF NULLIFICATION.—If a cosmetic ingredient statement is nullified under this section, no person shall import, export, or otherwise distribute the cosmetic product that was the subject of the cosmetic ingredient statement.

''(e) ADDITIONAL REQUIREMENTS.—

''(1) SAFETY REQUIREMENTS.—In filing each cosmetic ingredient statement for each cosmetic product, the responsible person shall include an attestation that the safety of the product, including the individual ingredients of such product and the product as a whole, has been substantiated. In the case of a cosmetic ingredient statement that includes a range of possible amounts (as described in subsection (c)(2)(E)), the responsible person shall include an attestation that the safety of the full range in the finished product has been substantiated.

''(2) ABBREVIATED FILING.—The Food and Drug Administration shall provide for an abbreviated renewal process for any such filing with respect to which there has been no change since the responsible person submitted the previous filing.

''(3) CHANGES TO INFORMATION.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the responsible person shall notify the Food and Drug Administration within 60 days of any change to the information required to be in a cosmetic ingredient statement, including discontinuation of the manufacture of a cosmetic product, except that notification under this paragraph is not required for a change in—

''(i) the amount of an existing ingredient if it is within the range previously reported under subsection (c)(2)(E); or

''(ii) the addition or subtraction of a fragrance, flavor, or color, or such other interchangeable ingredients specified by the Food and Drug Administration in regulations or guidance, previously reported as a potential ingredient under subsection (c)(2)(E), if, in the case of an addition of such an ingredient, the amount is within the range previously reported.

''(B) SMALL BUSINESS.—The Food and Drug Administration shall allow a responsible person that is a business that meets the applicable industry-based small business size stand-

ard established by the Administrator of the Small Business Administration under section 3 of the Small Business Act to have an additional time period, as determined by the Secretary, to submit any change to the information required to be in a cosmetic ingredient statement as described in subparagraph (A).

''(f) COSMETIC PRODUCTS LIST.—At the time of the initial submission of any cosmetic ingredient statement under this section, the Food and Drug Administration shall assign a unique cosmetic product listing number to the cosmetic ingredient statement. Based on such cosmetic ingredient statements, the Food and Drug Administration shall compile and maintain a list of cosmetic products distributed in the United States, including the ingredients of each such product, and shall make available such list to any State, upon request. Information disclosed to a State that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC INGREDIENT STATEMENT.

''(a) SUSPENSION OF REGISTRATION OF A FACILITY.—If the Food and Drug Administration determines

that a cosmetic formulation or cosmetic product manufactured, processed, packed, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans, the Food and Drug Administration may suspend the registration of a facility.

''(b) SUSPENSION OF COSMETIC INGREDIENT STATEMENT.—If the Food and Drug Administration determines that a cosmetic product manufactured in a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans, the Food and Drug Administration may suspend the cosmetic ingredient statement of that product.

''(c) NOTICE OF SUSPENSION.—Before suspending a facility registration or a cosmetic ingredient statement under this section, the Food and Drug Administration shall provide—

''(1) notice to the facility or responsible person, as appropriate, of the intent to suspend the facility registration or the cosmetic ingredient statement, which shall specify the basis of the determination by the Food and Drug Administration that the facility registration or the cosmetic ingredient statement should be suspended; and

''(2) an opportunity, within 2 business days of the notice provided under paragraph (1), for the facility or responsible person, as appropriate, to address the reasons for possible suspension of the facility registration or cosmetic ingredient statement.

''(d) REINSTATEMENT.—Upon a determination by the Food and Drug Administration that adequate grounds do not exist to continue the suspension actions, the Food and Drug Administration shall promptly vacate the suspension and reinstate the registration of the facility or the cosmetic ingredient statement.

''(e) EFFECT OF SUSPENSION.—

''(1) REGISTRATION.—If the registration of a facility is suspended under this section, no person shall import or export cosmetics or otherwise distribute cosmetics from such facility.

''(2) COSMETIC INGREDIENT STATEMENT.—If the cosmetic ingredient statement for a cosmetic product is suspended under this section, no person shall import or export such cosmetic product or otherwise distribute in the United States such cosmetic product that is the subject of such statement.

''(f) NO DELEGATION.—The authority conferred by this section to issue an order to suspend a registration

or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.''.