## **AMENDMENT**

## Offered by M .

## [Page/line numbers refer to OTCMONOGRAPH\_05, dated January 12, 2018]

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

1	SEC. 105. REGISTRATION OF COSMETICS FACILITIES AND
2	COSMETIC INGREDIENT STATEMENTS.
3	(a) Amendments.—Chapter VI of the Federal Food,
4	Drug, and Cosmetic Act (21 U.S.C. 361 et seq.) is amend-
5	ed by adding at the end the following:
6	"SEC. 604. DEFINITIONS.
7	"In this chapter:
8	"(1) Cosmetic formulation.—The term 'cos-
9	metic formulation' means a preparation of cosmetic
10	raw materials with a qualitatively and quantitatively
11	set composition.
12	"(2) Cosmetic product.—The term 'cosmetic
13	product' means a cosmetic comprised of a specified
14	set of ingredients, which may come in a range of
15	possible amounts for each ingredient and which may
16	include a variety of fragrances and colors, and in
17	some specific cosmetic applications, flavors.

1	"(3) Facility.—The term 'facility' includes
2	any factory, warehouse, or establishment (including
3	a factory, warehouse, or establishment of an im-
4	porter) that manufactures, processes, packs, or holds
5	cosmetic products or cosmetic formulations, or any
6	other entity whose name and address appear on the
7	label of a cosmetic product. Such term does not in-
8	clude—
9	"(A) beauty shops and salons that do not
10	otherwise manufacture, process, or package cos-
11	metics at that location;
12	"(B) cosmetic product retailers, including
13	individual sales representatives, retail distribu-
14	tion facilities, retail warehouses, and phar-
15	macies, that do not otherwise manufacture,
16	process, or package cosmetics at that location;
17	"(C) hospitals, physicians' offices, and
18	health care clinics;
19	"(D) public health agencies and other non-
20	profit entities that provide cosmetics directly to
21	the consumer;
22	"(E) hotels and other entities that provide
23	complimentary cosmetics to guests;

1	"(F) trade shows and other venues where
2	cosmetic product samples are provided free of
3	charge;
4	"(G) domestic manufacturers with less
5	than \$100,000 in gross annual sales of cosmetic
6	products, except for any manufacturer that is
7	engaged in the manufacturing, processing, or
8	distributing of products intended to be injected
9	under the skin or into the eye, including tattoo
10	ink;
11	"(H) entities that manufacture or com-
12	pound cosmetic products solely for use in re-
13	search, teaching, or pilot plant production and
14	not for sale.
15	"(4) Foreign facility.—The term 'foreign fa-
16	cility' means a facility that manufactures, processes,
17	packs, or holds, a cosmetic formulation or cosmetic
18	product that is exported to the United States with-
19	out further processing or packaging inside the
20	United States. A cosmetic is not considered to have
21	undergone further processing or packaging for pur-
22	poses of this definition solely on the basis that label-
23	ing was added or that any similar activity of a de
24	minimis nature was carried out with respect to the
25	cosmetic.

1	"(5) Nonfunctional constituent.—The
2	term 'nonfunctional constituent' means any sub-
3	stance that is an incidental component of an ingre-
4	dient, a breakdown product of an ingredient or a by-
5	product of the manufacturing process that has not
6	been intentionally added as a separate substance and
7	serves no technical function in the cosmetic.
8	"(6) Responsible Person.—The term 're-
9	sponsible person' means—
10	"(A) the brand owner, operator, or agent
11	in charge who is the domestic or foreign manu-
12	facturer, processor, or entity whose name ap-
13	pears on the label of a cosmetic product or a
14	cosmetic formulation distributed in the United
15	States, except for entities described in subpara-
16	graphs (A) through (H) of paragraph (3); or
17	"(B) a contract manufacturer who provides
18	cosmetic products to the entities described in
19	subparagraphs (A) through (H) of paragraph
20	(3).
21	"SEC. 605. REGISTRATION OF COSMETIC FACILITIES.
22	"(a) Registration and Fees for Existing Man-
23	UFACTURING OR PROCESSING OF COSMETICS.—
24	"(1) REGISTRATION, IN GENERAL.—Each re-
25	sponsible person engaged in manufacturing, or proc-

1 essing, or whose name appears on the label of a cos-2 metic product or a cosmetic formulation distributed 3 in the United States shall register all of the responsible person's facilities with the Food and Drug Ad-5 ministration. A responsible person required to reg-6 ister under this subsection shall, not later than 90 7 days after the Secretary announces the establish-8 ment of an electronic registration system for pur-9 poses of this section, submit a registration utilizing 10 such system which shall be effective for fiscal year 2018. 11 12 "(2) Fees.—If the average gross annual sales 13 in the United States of cosmetic products of all of 14 the responsible person's facilities registered under 15 paragraph (1) for the previous 3-year period is 16 greater than \$500,000, a registration shall not be 17 complete under this subsection until the responsible 18 person has paid any registration fee required. 19 "(b) Registration for Existing Packing or HOLDING FACILITIES.—Each facility engaged in packing 20 21 or holding a cosmetic product distributed in the United States shall register with the Food and Drug Administra-23 tion. Each facility required to register under this subsection shall, not later than 90 days after the Secretary announces the establishment of an electronic registration

- 1 system for purposes of this section, submit a registration
- 2 utilizing such system which shall be effective for fiscal
- 3 year 2018.
- 4 "(c) Registration by New Facilities.—A respon-
- 5 sible person first engaging after the date of enactment of
- 6 the Cosmetic Safety Enhancement Act of 2018 in an activ-
- 7 ity that would require it to register under subsection (a)
- 8 or (b) shall register with the Food and Drug Administra-
- 9 tion immediately upon engaging in such activity, and
- 10 thereafter in accordance with subsection (a) or (b).
- 11 "(d) Changes to Information.—A responsible
- 12 person that submitted a registration under this section
- 13 shall notify the Food and Drug Administration of any
- 14 change to the information required under subsection (a)
- 15 or (b) not later than 30 days after the date of such
- 16 change, unless otherwise specified by the Food and Drug
- 17 Administration.
- 18 "(e) Annual Registration Renewal.—A respon-
- 19 sible person that continues to engage in any activity that
- 20 would require registration under subsection (a) or (b) shall
- 21 submit to the Secretary an annual registration during the
- 22 first quarter of the fiscal year for which such renewed reg-
- 23 istration shall be effective.
- 24 "(f) Format; Contents.—

1	"(1) ELECTRONIC FORMAT.—Each registration
2	shall be submitted using an electronic format, as
3	specified in a registration form provided by the Food
4	and Drug Administration.
5	"(2) Contents.—The registration shall con-
6	tain the following information:
7	"(A) Each facility's name and full address,
8	identifying the precise physical location of the
9	facility.
10	"(B) The identity of the facility, including
11	the unique facility identifier, if any, previously
12	assigned by the Food and Drug Administration
13	to the facility under subsection (g).
14	"(C) All business trading names used by
15	the facility.
16	"(D) The product category or categories of
17	each cosmetic product or cosmetic formulation
18	manufactured, processed, packed, or held at the
19	facility or on whose label the facility's name
20	and address appear.
21	"(E) The type or types of activities con-
22	ducted at the facility (such as manufacturing,
23	processing, packing, or holding).

1	"(F) The name, title, street address, tele-
2	phone number, and electronic contact informa-
3	tion of the emergency contact for the facility.
4	"(G) In the case of a foreign facility, the
5	name, street address, telephone number, emer-
6	gency contact information for the facility, the
7	name of the United States agent for the facil-
8	ity, and the phone number and electronic con-
9	tact information of the United States agent.
10	"(H) The name, title, street address, tele-
11	phone number, and electronic contact informa-
12	tion of the individual submitting the registra-
13	tion.
14	"(I) An assurance that the Food and Drug
15	Administration will be permitted to inspect such
16	facility at the times and in the manner per-
17	mitted by this Act.
18	"(J) Additional information pertaining to
19	the facility or to the cosmetic products or cos-
20	metic formulations manufactured, processed,
21	packed, or held at the facility, or on whose label
22	the facility's name and address appear, includ-
23	ing all brand names known to consumers, as
24	the Food and Drug Administration may require
25	by regulation.

1	"(3) Abbreviated registration.—The Food
2	and Drug Administration shall provide for an abbre-
3	viated registration renewal process for any facility
4	that has not had any changes to such information
5	with respect to the facility or facilities involved since
6	the facility submitted the preceding registration.
7	"(g) Incomplete or Inaccurate Registra-
8	TION.—
9	"(1) In general.—Not earlier than 10 days
10	after providing notice of the intent to cancel a reg-
11	istration and the basis for such cancellation, the
12	Food and Drug Administration may cancel a reg-
13	istration under this section if the Food and Drug
14	Administration has reasonable grounds to believe
15	that the registration was not properly completed or
16	updated in accordance with this section, if a re-
17	quired registration fee has not been paid within 30
18	days, or if the registration otherwise contains false,
19	incomplete, or inaccurate information.
20	"(2) Timely update or correction.—If, not
21	later than 7 days after receipt of a notice of intent
22	to cancel, the facility corrects the registration in ac-
23	cordance with the basis for the cancellation, and the
24	required registration fee, if any, is paid, the Food

1 and Drug Administration shall not cancel such reg-2 istration. 3 "(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. 6 7 "(i) REGISTRY OF FACILITIES.— "(1) IN GENERAL.—The Food and Drug Ad-8 9 ministration shall compile, maintain, and update a 10 registry of facilities that are registered under this 11 section, and shall remove from such registry the 12 name of any facility whose registration under this 13 section is cancelled. The registry shall be publicly 14 available. 15 "(2) Public availability exceptions.—In-16 formation derived from the registry or registration 17 documents that discloses the residential address of a 18 responsible person, facility, or that discloses specific 19 facilities where specific cosmetic products are manu-20 factured or processed shall not be subject to disclo-21 sure under section 552 of title 5, United States 22 Code. 23 "SEC. 606. COSMETIC INGREDIENT STATEMENTS. 24 "(a) IN GENERAL.—For each cosmetic product, the responsible person shall submit to the Food and Drug Ad-

1	ministration a cosmetic ingredient statement, at such time
2	and in such manner as the Food and Drug Administration
3	may prescribe. The cosmetic ingredient statement shall
4	not become effective until the responsible person pays any
5	applicable fee required.
6	"(b) Submission of a Cosmetic Ingredient
7	STATEMENT.—
8	"(1) Existing cosmetic products.—In the
9	case of a cosmetic product that is marketed on the
10	date of enactment of the Cosmetic Safety Enhance-
11	ment Act of 2018, the responsible person shall sub-
12	mit a cosmetic ingredient statement not later than
13	July 30, 2018. The responsible person shall submit
14	to the Food and Drug Administration an annual re-
15	newal of such statement during the first quarter of
16	the fiscal year for which such renewed statement is
17	applicable.
18	"(2) Cosmetic ingredient statement for
19	NEW COSMETIC PRODUCTS.—
20	"(A) In General.—Except as provided
21	under subparagraph (B), in the case of a cos-
22	metic product that is first marketed after the
23	date of enactment of the Cosmetic Safety En-
24	hancement Act of 2018 or a cosmetic product
25	that is reformulated after such date of enact-

1	ment, the responsible person shall submit a cos-
2	metic ingredient statement to the Food and
3	Drug Administration prior to first marketing
4	the new cosmetic product or the reformulated
5	cosmetic product, and annually thereafter dur-
6	ing the first quarter of the fiscal year for which
7	the cosmetic ingredient statement is applicable.
8	"(B) SMALL BUSINESSES.—The Food and
9	Drug Administration shall allow a responsible
10	person that is a business that meets the appli-
11	cable industry-based small business size stand-
12	ard established by the Administrator of the
13	Small Business Administration under section 3
14	of the Small Business Act to have an additional
15	time period, as determined by the Secretary, to
16	submit an initial new cosmetic ingredient state-
17	ment under subparagraph (A). Such responsible
18	person shall submit a cosmetic ingredient state-
19	ment annually thereafter during the first quar-
20	ter of the fiscal year.
21	"(C) Definition.—A cosmetic product
22	shall not be considered first marketed or refor-
23	mulated after the date of enactment under sub-
24	paragraph (A) if the only change in such prod-
25	uct is in—

1	"(i) the amount of an existing ingre-
2	dient if it is within the range previously re-
3	ported under subsection (c)(2)(E); or
4	"(ii) the addition or subtraction of a
5	fragrance, flavor, or color, or such other
6	interchangeable ingredients specified by
7	the Food and Drug Administration in reg-
8	ulations or guidance, previously reported
9	as a potential ingredient under subsection
10	(c)(2)(E), if, in the case of such an addi-
11	tion, the amount is within the range pre-
12	viously reported.
13	"(c) Format; Contents.—
14	"(1) Form.—For each cosmetic product, the
15	cosmetic ingredient statement shall be submitted
16	using an electronic format, as specified in a cosmetic
17	and ingredient form provided by the Food and Drug
18	Administration.
19	"(2) Contents.—The cosmetic ingredient
20	statement shall include the following information:
21	"(A) The unique identifier, assigned under
22	section 605(g), as applicable, of—
23	"(i) the facility or facilities where the
24	cosmetic product is manufactured, proc-
25	essed, packed, or held or, if the same cos-

1	metic product is manufactured, processed,
2	packed, or held in more than one facility,
3	the unique facility identifier of each facility
4	where it is manufactured, processed,
5	packed, or held; and
6	"(ii) the facility whose name and ad-
7	dress appear on the label, unless the state-
8	ment is filed by a contract manufacturer,
9	described in section $604(6)(B)$ .
10	"(B) The brand name and the full name
11	for the cosmetic product as it appears on the
12	label.
13	"(C) The cosmetic product listing number,
14	if any, previously assigned by the Food and
15	Drug Administration under subsection (f) to
16	the cosmetic product.
17	"(D) The applicable cosmetic category for
18	the cosmetic product.
19	"(E) A list of ingredients in the cosmetic
20	product, including a range of possible amounts
21	of each ingredient, and with each ingredient
22	identified by the name adopted in regulations
23	promulgated by the Food and Drug Adminis-
24	tration, if any, or by the common or usual

1	name of the ingredient. The cosmetic ingredient
2	statement shall contain—
3	"(i) a list of fragrances, flavors, and
4	colors that may be included in the product,
5	interchangeably, with ranges of possible
6	amounts, which shall include—
7	"(I) in the case of fragrances
8	that are purchased from a fragrance
9	supplier, the fragrances shall be iden-
10	tified by the name or code provided by
11	the supplier, and include the name
12	and contact information for the fra-
13	grance supplier;
14	"(II) in the case of flavors that
15	are purchased from a flavor supplier,
16	the flavors shall be identified by the
17	name or code provided by the sup-
18	plier, and include the name and con-
19	tact information for the flavor sup-
20	plier; and
21	"(III) if requested by the Food
22	and Drug Administration by means of
23	a written notification to the fragrance
24	or flavor supplier, the complete list of
25	ingredients in specific fragrances or

1	flavors (and the supplier shall have 30
2	days to provide such list to the Food
3	and Drug Administration); and
4	"(ii) other appropriate interchange-
5	able ingredients as the Food and Drug Ad-
6	ministration may specify in regulations or
7	guidance that may be included in the prod-
8	uct, with ranges of possible amounts.
9	"(F) The title and full contact information
10	of each individual submitting the statement.
11	"(G) Such additional information per-
12	taining to the cosmetic product as the Food and
13	Drug Administration may require.
14	"(3) Cosmetic ingredient statement for
15	CERTAIN SMALL BUSINESSES.—
16	"(A) In General.—Notwithstanding any
17	other provision of this subsection, the Food and
18	Drug Administration may permit a simplified
19	cosmetic ingredient statement under this sec-
20	tion for a responsible person that—
21	"(i) is a business that meets the appli-
22	cable industry-based small business size
23	standard established by the Administrator
24	of the Small Business Administration

1	under section 3 of the Small Business Act;
2	and
3	"(ii) has had an average of less than
4	\$500,000 in annual domestic cosmetic
5	sales over the previous 3 years.
6	"(B) Contents.—A responsible person
7	described in subparagraph (A) shall include in
8	each cosmetic ingredient statement under this
9	section, at a minimum, a list of ingredients in
10	the cosmetic product and the applicable cos-
11	metic category for the cosmetic product. If a
12	cosmetic product includes a fragrance or flavor
13	purchased from a fragrance or flavor supplier,
14	the responsible person must, at a minimum, in-
15	clude a list of all fragrances and flavors con-
16	tained in the cosmetic product and contact in-
17	formation for the fragrance or flavor supplier,
18	including the supplier's name, street address,
19	telephone number, and electronic contact infor-
20	mation. In the case of a written notification
21	under paragraph (2)(E)(i)(III) provided by the
22	Food and Drug Administration to the respon-
23	sible person for the cosmetic manufacturer, the
24	Food and Drug Administration may request,
25	from the fragrance or flavor supplier, the com-

1	plete list of ingredients in specific fragrances or
2	flavors, and the supplier shall have 30 days to
3	provide such list to the Food and Drug Admin-
4	istration.
5	"(d) Incomplete or Inaccurate Cosmetic In-
6	GREDIENT STATEMENT.—
7	"(1) In general.—Not earlier than 10 days
8	after providing notice under paragraph (2), the Food
9	and Drug Administration may nullify a cosmetic in-
10	gredient statement filed under this section if the
11	Food and Drug Administration has reasonable
12	grounds to believe that the cosmetic ingredient state-
13	ment was not completed or updated in accordance
14	with this section or otherwise contains false, incom-
15	plete, or inaccurate information.
16	"(2) Notice of nullification.—A nullifica-
17	tion under paragraph (1) shall be preceded by notice
18	to the responsible person of the intent to cancel the
19	cosmetic ingredient statement and the basis for such
20	cancellation.
21	"(3) Timely update or correction.—If the
22	cosmetic ingredient statement is appropriately up-
23	dated or corrected not later than 7 days after notice
24	is provided under paragraph (1), the Food and Drug

1	Administration shall not nullify such cosmetic ingre-
2	dient statement.
3	"(4) Effect of nullification.—If a cos-
4	metic ingredient statement is nullified under this
5	section, no person shall import, export, or otherwise
6	distribute the cosmetic product that was the subject
7	of the cosmetic ingredient statement.
8	"(e) Additional Requirements.—
9	"(1) Safety requirements.—In filing each
10	cosmetic ingredient statement for each cosmetic
11	product, the responsible person shall include an at-
12	testation that the safety of the product, including
13	the individual ingredients of such product and the
14	product as a whole, has been substantiated. In the
15	case of a cosmetic ingredient statement that includes
16	a range of possible amounts (as described in sub-
17	section $(c)(2)(E)$ ), the responsible person shall in-
18	clude an attestation that the safety of the full range
19	in the finished product has been substantiated.
20	"(2) Abbreviated filing.—The Food and
21	Drug Administration shall provide for an abbre-
22	viated renewal process for any such filing with re-
23	spect to which there has been no change since the
24	responsible person submitted the previous filing.
25	"(3) Changes to information.—

1	"(A) IN GENERAL.—Except as provided in
2	subparagraph (B), the responsible person shall
3	notify the Food and Drug Administration with-
4	in 60 days of any change to the information re-
5	quired to be in a cosmetic ingredient statement,
6	including discontinuation of the manufacture of
7	a cosmetic product, except that notification
8	under this paragraph is not required for a
9	change in—
10	"(i) the amount of an existing ingre-
11	dient if it is within the range previously re-
12	ported under subsection (c)(2)(E); or
13	"(ii) the addition or subtraction of a
14	fragrance, flavor, or color, or such other
15	interchangeable ingredients specified by
16	the Food and Drug Administration in reg-
17	ulations or guidance, previously reported
18	as a potential ingredient under subsection
19	(c)(2)(E), if, in the case of an addition of
20	such an ingredient, the amount is within
21	the range previously reported.
22	"(B) SMALL BUSINESS.—The Food and
23	Drug Administration shall allow a responsible
24	person that is a business that meets the appli-
25	cable industry-based small business size stand-

1	ard established by the Administrator of the
2	Small Business Administration under section 3
3	of the Small Business Act to have an additional
4	time period, as determined by the Secretary, to
5	submit any change to the information required
6	to be in a cosmetic ingredient statement as de-
7	scribed in subparagraph (A).
8	"(f) Cosmetic Products List.—At the time of the
9	initial submission of any cosmetic ingredient statement
10	under this section, the Food and Drug Administration
11	shall assign a unique cosmetic product listing number to
12	the cosmetic ingredient statement. Based on such cosmetic
13	ingredient statements, the Food and Drug Administration
14	shall compile and maintain a list of cosmetic products dis-
15	tributed in the United States, including the ingredients
16	of each such product, and shall make available such list
17	to any State, upon request. Information disclosed to a
18	State that is exempt from disclosure under section
19	552(b)(4) of title 5, United States Code, shall be treated
20	as a trade secret and confidential information by the
21	State.
22	"SEC. 607. SUSPENSION OF REGISTRATION OR COSMETIC
23	INGREDIENT STATEMENT.
24	"(a) Suspension of Registration of a Facil-
25	ITY.—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 4 health consequences or death to humans, the Food and Drug Administration may suspend the registration of a 6 facility. 7 "(b) Suspension of Cosmetic Ingredient State-8 MENT.—If the Food and Drug Administration determines that a cosmetic product manufactured in a registered facility has a reasonable probability of causing serious ad-10 verse health consequences or death to humans, the Food 12 and Drug Administration may suspend the cosmetic ingre-13 dient statement of that product. 14 "(c) Notice of Suspension.—Before suspending a 15 facility registration or a cosmetic ingredient statement under this section, the Food and Drug Administration 16 17 shall provide— 18 "(1) notice to the facility or responsible person, 19 as appropriate, of the intent to suspend the facility 20 registration or the cosmetic ingredient statement, 21 which shall specify the basis of the determination by 22 the Food and Drug Administration that the facility 23 registration or the cosmetic ingredient statement

24

should be suspended; and

1	"(2) an opportunity, within 2 business days of
2	the notice provided under paragraph (1), for the fa-
3	cility or responsible person, as appropriate, to ad-
4	dress the reasons for possible suspension of the facil-
5	ity registration or cosmetic ingredient statement.
6	"(d) Reinstatement.—Upon a determination by
7	the Food and Drug Administration that adequate grounds
8	do not exist to continue the suspension actions, the Food
9	and Drug Administration shall promptly vacate the sus-
10	pension and reinstate the registration of the facility or the
11	cosmetic ingredient statement.
12	"(e) Effect of Suspension.—
13	"(1) Registration.—If the registration of a
14	facility is suspended under this section, no person
15	shall import or export cosmetics or otherwise dis-
16	tribute cosmetics from such facility.
17	"(2) Cosmetic ingredient statement.—If
18	the cosmetic ingredient statement for a cosmetic
19	product is suspended under this section, no person
20	shall import or export such cosmetic product or oth-
21	erwise distribute in the United States such cosmetic
22	product that is the subject of such statement.
23	"(f) No Delegation.—The authority conferred by
24	this section to issue an order to suspend a registration

- 1 or vacate an order of suspension shall not be delegated
- 2 to any officer or employee other than the Commissioner.".

