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. ADVERSE EVENT REPORTS FOR COSMETICS.

Chapter VI of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361 et seq.), as amended by section 103(a), is further amended by adding at the end the following:

"SEC. 604. ADVERSE EVENT REPORTING FOR COSMETICS.

"(a) IN GENERAL.—With respect to any cosmetic product distributed in the United States, the responsible person shall submit, in electronic format, to the Food and Drug Administration—

"(1) a report of any serious adverse event associated with such cosmetic product, when used in the United States, accompanied by a copy of the label on or with the retail packaging of the cosmetic;

"(2) any new medical information, related to a submitted serious adverse event report, that is received by the responsible person; and

''(3) an annual report for all adverse events for which information has received by the responsible person.

''(b) DEFINITIONS.—In this section:

''(1) An 'adverse event' for a cosmetic product is a health-related event associated with the use of this product that is adverse.

''(2) A 'serious adverse event' for a cosmetic product is an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant adverse health condition, disability or incapacity;

''(v) congenital anomaly or birth defect; or

''(vi) significant disfigurement, including serious and persistent rashes and infections, burns, or significant hair loss; or

''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

''(c) SUBMISSION OF REPORTS.—

''(1) SERIOUS ADVERSE EVENT REPORTS.—Except as provided in paragraph (2), the responsible person shall submit a serious adverse event report to the Food and Drug Administration not later than 15 business days after information concerning the adverse event is received. If a serious adverse event report for a cosmetic with drug properties is filed using Form FDA 3500A (or any successor form developed for such purpose) or its electronic equivalent for over-the-counter drugs, the responsible person shall not have to submit a duplicative serious adverse event report under this section. Serious adverse event reports under this section shall be made available on the Internet website of the Food and Drug Administration.

''(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Food and Drug Administration any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, and shall submit such information not later than 15 business days after the new information is received by the responsible person.

''(3) SEMIANNUAL REPORT.—

"(A) IN GENERAL.—Not later than January 1 and July 1 of each year, the responsible person shall submit an electronic report for the prior calendar year for each cosmetic product marketed during that year.

"(B) CONTENTS.—Each report under this paragraph shall contain a summary of all adverse events received during the reporting period, a complete list of individual reports, and an estimate of the total number of product units estimated to have been distributed to consumers during such period. The report shall not include consumer complaints that are solely regarding efficacy and do not contain any information about an adverse event. The Food and Drug Administration shall further specify the contents of the annual electronic report by regulation or guidance.

"(4) EXEMPTION.—The Food and Drug Administration may establish by regulation an exemption to any of the requirements under this subsection if the Food and Drug Administration determines that such exemption is supported by adequate evidence and would have no adverse effect on public health.

''(d) REQUIREMENTS.—

''(1) IN GENERAL.—Each serious adverse event report under this section shall be submitted to the Food and Drug Administration using an electronic system of the Food and Drug Administration. The Food and Drug Administration shall make such electronic system available not later than 1 year after the date of enactment of the Cosmetic Safety Enhancement Act of 2018.

''(2) MODIFICATION.—The format of the reporting system may be modified by the Food and Drug Administration and the reports may include additional information. The Food and Drug Administration may, in guidance, further specify the format and contents of required reports.

''(3) SCOPE OF SERIOUS ADVERSE EVENT REPORT.—A serious adverse event report (including all information submitted in the initial report or added later) submitted to the Food and Drug Administration under subsection (a) includes—

''(A) a report under section 756 with respect to safety and related to a specific cosmetic product;

''(B) a record about an individual who suffered the serious adverse event under section 552a of title 5, United States Code;

''(C) a medical or similar file documenting the serious adverse event, the disclosure of which would constitute a violation of section 552(b)(6) of such title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted; and

''(D) contact information for the individual reporting the serious adverse event.

''(4) RESPONSIBILITY TO GATHER INFORMATION.—After an individual initiates the reporting of a serious adverse event, the responsible person for the cosmetic product shall actively gather all of the information to complete and file the report with the Food and Drug Administration.

''(5) NO ADVERSE EVENTS TO REPORT.—The Food and Drug Administration shall provide an option as part of the electronic registration process for the responsible person to indicate if such responsible person had no adverse events to report over the previous year. With respect to a responsible person who received no adverse event reports for a year, the annual adverse event report requirement may be met

by indicating no such events on the annual registration form.

''(e) LIMITATION WITH RESPECT TO ADVERSE EVENT REPORTS.—The submission of an adverse event report in compliance with subsection (a) shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.

''(f) CONTACT INFORMATION.—The label of a cosmetic shall bear the domestic telephone number or electronic contact information, and it is encouraged that the label include both the telephone number and electronic contact information, through which the responsible person may receive a report of an adverse event.

''(g) MAINTENANCE OF RECORDS.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

''(h) AVAILABILITY TO STATES.—The Food and Drug Administration shall make available records submitted under this section 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.

''(i) EFFECTIVE DATE OF REQUIREMENT WITH RESPECT TO SERIOUS ADVERSE EVENTS.—The requirement under this section to report serious adverse events shall become effective on the date that the Food and Drug Administration publicizes the availability of the electronic system described in subsection (d)(1).''.

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