Modernization of Cosmetics Regulation Act of 2018	
SECTION 1. Short Title	
• This Act may be cited as the "Modernization of Cosmetics Regulation Act of 2018".	
SECTION 2. Cosmetics	
• Amends Chapter VI of the Federal Food, Drug, and Cosmetic Act by inserting the following:	
Sec. 604. Definitions.	• Defines terms for purposes of the Cosmetics Safety Act, including cosmetic product, facility, responsible person, serious adverse event, adverse event, and other terms.
Sec. 605. Adverse events.	• Requires reports of serious adverse events to be submitted to the Secretary within 15 days of receipt of such report. • Requires that records related to adverse events be maintained for a period of 6 years. • Provides the Secretary the ability to request in writing a list of ingredients in specific fragrances or flavors listed, if there are reasonable grounds to believe that an ingredient caused a serious adverse event. • Clarifies that submissions of adverse event reports to the Secretary do not constitute an admission that such product caused or contributed to the adverse event.
Sec. 606. Good manufacturing practices.	• The Secretary shall establish through regulation good manufacturing practices (GMPs) for cosmetic facilities consistent with national and international standards. Such GMPs shall be intended to protect the public health and ensure that cosmetic products do not cause serious adverse health consequences or death. • Ensures that FDA accounts for the size and scope of businesses in establishing GMPs and develop standards that include simplified GMPs developed in consultation with the Small Business Administration and may include longer compliance deadlines.
Sec. 607. Registration.	• Requires an initial registration for existing cosmetic facilities that manufacture or process cosmetic products. Such facilities must register with the Secretary within 1 year after date of enactment. • Any new cosmetic facility that begins manufacturing or processing cosmetic products is required to register with the Secretary no later than 60 days after first engaging in such activities. • Requires facility registrations to be renewed biennially. • Requires certain changes or additions to a facility registration or ingredient listing to be made within 60 days. • Provides for an abbreviated registration renewal process if there are no changes to a facility registration or cosmetic ingredient listing. • Streamlines registration by enabling contract manufacturers to register facilities that manufacture or process cosmetic products on behalf of a responsible person, and requires only a single facility registration if a contract manufacturer is manufacturing or processing its own cosmetic products or products for multiple responsible persons. • Requires an assurance that the facility will submit to inspection. • Requires an ingredient listing for cosmetic products manufactured or processed in such facility. This ingredient listing requires certain

	information including a list of fragrances, flavors, or colors identified using the name or code provided by the supplier. • Requires that, following a final determination of safety by the Secretary, the ingredient listing include the range of amounts of such ingredients in the cosmetic product for which Secretary specified conditions of use or tolerances. • Requires an assurance that the cosmetic product meets the safety standard under section 608, and that the responsible person will maintain adverse event records to section 605. • Provides that if the Secretary finds that there is reasonable probability that a cosmetic product may be causing serious adverse health consequences or death to humans, the Secretary may suspend the ingredient listing of the product, or if other products may be similarly affected due to a failure that cannot be isolated to a single product or product line, then the Secretary may suspend the facility registration. • Provides for a notice and opportunity to address the reasons for a possible suspension of the facility registration or cosmetic ingredient listing, in addition to a hearing on such suspension and a corrective action plan. If the Secretary no longer has reason to continue the suspension, the registration of the facility or cosmetic ingredient listing will be reinstated.
Sec. 608. Safety Standard.	• Establishes a safety standard for cosmetics and cosmetic products that such products are considered safe if there is a reasonable certainty that the cosmetic or cosmetic product is not injurious to health under conditions of use suggested or recommended in the labeling, or under ordinary conditions of use if no conditions of use are suggested or recommended in the label. • Provides that a cosmetic ingredient may not be considered unsafe solely because it can cause minor adverse health reactions, such as minor and transient allergic reactions or minor and transient skin irritations in some users. • Provides that coal-tar hair dye shall meet the conditions of 601(a) unless the Secretary has issued a final determination for an ingredient found in coal-tar hair dye.
Sec. 609. Labeling.	• Requires cosmetic products in interstate commerce be labeled with certain information, including the list of ingredients submitted under section 607(b) in order of predominance and where to report adverse events. Requires that the label include, following a final safety determination by the Secretary on an ingredient used in a cosmetic product, information related to related to the conditions of use. • Requires cosmetic products for professional use to clearly state on the label that the product is only to be used by licensed professionals.
Sec. 610. Ingredient Review.	• Requires that no later than 18 months after the date of enactment, the Secretary shall identify no less than 10 ingredients or non-functional constituents that the Secretary proposes to be assessed for purposes of public health. • Requires a process for public comment and input for States to inform the identification of the ingredients or non-functional constituents.

	• Clarifies that upon completion of the initial safety assessments and determinations, or if the Secretary determines additional ingredients should be reviewed for purposes of public health, the Secretary may identify additional ingredients. • Allows the Secretary to remove an ingredient or non-functional constituent from the final list after notice and comment. • Requires the Secretary to request scientific data for at least one ingredient per year, and provide a public comment period. • Requires the Secretary to initiate a safety assessment 90 days after the close of the comment period, or publically indicate that the safety assessment can be conducted by an accredited person. • The Secretary will make a final determination of safety or a determination of insufficient data after assessment of scientific evidence or the assessment conducted by an accredited person. • Establishes an accreditation scheme for persons to assess the safety of listed ingredients or non-functional constituents.
Sec. 611. Records.	• Provides the Secretary the authority to inspect records of cosmetic facilities and responsible persons if the Secretary has reasonable grounds to believe a cosmetic product is adulterated and can cause serious adverse health consequences.
Sec. 612. Small businesses.	• Exempts small businesses with gross annual sales in the previous 3-year period of less than $1M from GMP requirements, registration, and conditions of use labeling. • Does not exempt any business that manufacture or process the following cosmetic products: o regularly come into contact with the mucus membrane of the eye, o are injected, o are intended for internal use, or o are intended to alter appearance for more than 24 hours.
Sec. 613. Exemption for certain products and facilities.	• Products regulated as prescription drugs, medical devices, or OTC drugs will remain regulated as such and are not subject to the requirements of this chapter.
Sec. 614. Preemption.	• HELP Committee staff believe that a uniform federal standard for cosmetics regulation is an important component to this reform proposal. HELP Committee staff also recognize that work done by states to date warrants consideration. Staff would especially appreciate feedback from stakeholders regarding the best approach to federal preemption that works appropriately with the framework presented in this discussion draft.
Section 3. Enforcement.	
• Enforcement begins one year after the date of enactment. • Failure to register a facility with FDA, denial of inspection or access to records in accordance with this section, is a prohibited act, and falsification of adverse event reporting are considered prohibited Acts. • Products manufactured in unregistered facilities, manufactured in facilities that do not meet GMPs, or that contain ingredients in a manner inconsistent with a final safety determination are considered adulterated. • Products not appropriately labeled are considered misbranded.	

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<tr><td colspan="2">• Protects trade secrets as appropriate.</td></tr>
<tr><td colspan="2">SECTION 4. Records inspection.</td></tr>
<tr><td colspan="2">• Updates FDA’s authorities under Section 704 of the FFDCA.</td></tr>
<tr><td colspan="2">SECTION 5. Funding.</td></tr>
<tr><td colspan="2">• [$X] is authorized for each fiscal year 2019-2025 to carry out the amendments of this Act.</td></tr>
<tr><td colspan="2">SECTION 6. Reporting.</td></tr>
<tr><td colspan="2">• Further amends Chapter VI of the Federal Food, Drug, and Cosmetic Act by inserting the following:</td></tr>
<tr><td>Sec. 615. Reporting</td><td>• Requires an annual report to Congress – including information regarding:
o ingredients identified for review or of which a determination has been made,
o number and summary of serious adverse event reports,
o number of registered facilities,
o number of facilities inspection, and
o enforcement actions the Secretary has taken.</td></tr>
<tr><td colspan="2">GAO Report:
Requires a GAO report not later than 5 years after the date of enactment assessing:
o types of ingredients identified for a safety review,
o the level of coordination between the FDA and the States,
o process by which the FDA considers public input,
o FDA’s use of accredited third parties,
o time between identifying ingredients to be reviewed and issuance of an administrative order,
o how the FDA accounts for reports of serious adverse events, and
o frequency and type of inspections.</td></tr>
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