1388 Sutter Street, Suite 400
San Francisco, CA 94109-5400
Phone: 415.346.8223 Fax: 415.346.2975
www.safecosmetics.org | www.bcpp.org

March 15, 2018

Dear Chairman Alexander and Senator Murray:

Thank you for this opportunity to provide feedback on the "Modernization of Cosmetics Regulation Act of 2018" developed by bipartisan HELP Committee staff. Increased consumer awareness about the problem of toxic chemicals in cosmetics has led to an increased demand for safer products in the marketplace. Now hundreds of cosmetic manufacturers are fully disclosing ingredients (including fragrance) and avoiding the use of cancer-causing chemicals, reproductive toxicants and other unsafe chemicals, demonstrating these practices are not only possible, but profitable. Retailers, too, are becoming part of the solution by requiring the national brands they stock on their store shelves to eliminate chemicals of concern and practice a higher level of ingredient transparency

The 120 undersigned businesses, health associations and non-profit organizations believe that meaningful, health-protective federal cosmetic safety policy reform has an important role to play in ensuring that consumers are protected from exposure to unsafe chemicals in cosmetics. Based upon our preliminary analysis, we urge you to strengthen your draft bill in the following ways:

1. **Vulnerable Populations (Definitions – Sec. 604).**

   We recommend the bill include a definition of vulnerable populations that includes pregnant women, infants, children and workers that should be considered by the FDA and manufacturers when determining ingredient safety. Our suggested definition would read: "The term vulnerable population means a group of individuals within the general population who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.''

2. **Adverse Event Reporting (Sec. 605)**.

   The definition of serious adverse events included in the discussion draft is very good and should capture many our key concerns including persistent rashes and skin conditions, asthma and other serious respiratory concerns and significant hair loss. However, the focus on birth defects, while important, does not acknowledge the reproductive harm or other negative impacts on maternal health that can be and is being experienced by many salon workers who have long periods of exposure to beauty products. The area of adverse and serious adverse events should be expanded in the following ways:

a. The discussion draft's definition of "serious adverse event" should be expanded to include serious impacts to maternal health such as placentia previa, gestational diabetes, miscarriage.
b. The bill should require public notification and summary of serious adverse event reports and product recalls, facility suspensions and cosmetic ingredient suspensions through the FDA Adverse Event Reporting System (FAERS).
c. The bill should also require non-serious adverse events - such as acute reactions to a cosmetic product - be reported to the FDA annually.

3. **Fragrance Ingredient Disclosure (Registration – Sec. 607)**. Under the registration section of the discussion draft, a manufacturer – or its fragrance supplier - should be required to provide a full list of fragrance ingredients to the FDA, as opposed to simply providing names or codes provided by the supplier. This is a problem because fragrance is added to the vast majority of beauty and personal care products and can contain dozens – sometimes hundreds – of different chemicals linked to irritation, hormone disruption, cancer, developmental and reproductive toxicity. By exempting fragrance and flavors from FDA disclosure, the agency will not be getting the information it needs to fully and effectively regulate cosmetic ingredient safety, or even accurately assess the risks a specific fragrance chemical or flavorant may pose.

4. **Suspension of a Facility's Registration for Manufacturing Products Causing Serious Harm or Death (Registration – Sec. 607)**. The section of the discussion draft addressing suspension of the registration of a facility that is manufacturing a cosmetic product that is causing serious adverse health consequences or death is both too narrow in scope and too rigid in the conditions it places on the FDA. Two options are replacing this section of the discussion draft with a provision creating stronger FDA mandatory recall authority, or addressing the following concerns in the existing provision:

   a. This provision raises concern because it allows for suspension of a cosmetic manufacturer's facility registration if they are distributing a product that is likely to cause serious adverse health consequences or death, but *only* if the product is distributed in the U.S. and *only* if the FDA has a reasonable belief that the problem can't be traced to a single product. This suggests a manufacturer could be based in the US and selling an adulterated product abroad, yet the draft bill does not give the FDA the authority to stop distribution of the hazardous product.

   b. The bill does allow for suspension of an ingredient listing if the product has a reasonability probability of causing adverse health consequences or death. However, the FDA must inform companies in writing of their intent to suspend a facility or product, with the basis for the determination and recommendation for specific actions the company can take to avoid suspension. This is problematic because the FDA might not know what the ingredient(s) are that are causing adverse reactions or death, nor is it the agency's job to tell a manufacturer how to correct the problem – something the FDA simply may not know. Such a high bar for issuing a suspension, could slow down and hamper the FDA's ability to stop the distribution of dangers/ hazardous cosmetic products.

c. Further, the bill gives companies 2 business days to provide "a plan for addressing the reason for possible suspension" after receiving notice from the FDA of their intent to suspend a facility registration or cosmetic ingredient listing. The FDA should be given the authority to order a facility to immediately cease production and distribution of a product that is causing serious harm to public health or death – as opposed to waiting an additional 2 business days while the company generates a plan to address the proposed suspension.

d. The discussion draft should expand the legal definition of "adulterated cosmetics" to allow the FDA to deem a cosmetic product to be adulterated regardless of whether it is known which ingredient or ingredients is rendering the cosmetic injurious to users.

5. **Safety Standard (Sec. 608).** This section of the discussion draft 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." This safety standard has historically been applied to adulterated food (21 U.S. Code § 342) and adulterated cosmetics and has primarily been used to address pathogens, bacteria or known toxins not chronic health effects, which is the central focus of this stakeholder feedback. We instead support the use of the Food Quality Protection Act's "reasonable certainty of no harm" safety standard which would provide an extra safety factor for children, as well as tying the safety standard to "intended, known and foreseeable conditions of use" as opposed to label instructions.

6. **Ingredient Labeling (Sec. 609)**. We fully support the discussion draft's requirement that the ingredients in professional salon products appear on the product label. Nail and hair salon professionals work with a multitude of cosmetic products on a daily basis made with chemicals known or suspected to cause cancer, respiratory, neurological and reproductive harm. They need and deserve the same level of ingredient disclosure required by law for cosmetic products marketed to consumers, so they can make informed choices about the products they use and how to protect their health. We also would like to see the labeling section of the discussion draft expanded to require ingredient disclosure for any web-based sale of a cosmetic or personal care product. Although on pack disclosure of the ingredients in retail consumer cosmetic products became the law of the land with the passage of the Fair Packaging and Labeling Act (FPLA) in 1967, because e-commerce did not even become possible until 25 years later in 1991, the FPLA does not explicitly require nor address this type of ingredient disclosure. This is a problem because more and more consumers are doing their shopping online and are often in the dark as to what the ingredients are in the cosmetic products they are buying through web-based purchases.

   We would also like to see the labeling provision expanded to require disclosure of the constituent ingredients in any fragrances, flavors, or colors used in consumer or professional use cosmetic product. Two of the world's biggest cosmetic companies –

Unilever and P&G – and hundreds of smaller safe cosmetic companies have adopted voluntary fragrance ingredient disclosure policies, responding to consumer and worker demand for greater ingredient transparency and proving in the process of doing so that fragrance disclosure is not only possible, it is profitable. Supplier codes do not provide the ingredient information consumers and workers need to protect themselves from unsafe chemical exposures and make informed purchases.

7. **FDA Ingredient Review (Sec. 610).** We support the discussion draft's directive to the FDA to utilize consumer and industry feedback to identify the chemicals that should be prioritized for safety review by the agency including classes of cosmetic chemicals and non-functional constituents (aka contaminants). We also support that the FDA is directed to look at scientific evidence related to cumulative exposures and "pediatric exposures." We would like to see this provision expanded to include:

    a. FDA review of possible harm from "low dose exposures" to certain chemicals in cosmetics, particularly endocrine disrupting compounds which can be hormonally active at very low concentrations. When assessing safety, the FDA should also consider potential effects in humans of aggregate exposure to the ingredient or contaminant, or to any chemically or pharmacologically related substances, from use in cosmetics or other products.
    b. The potential negative health impacts emerging from exposures to vulnerable populations including pregnant women, infants, children and workers.
    c. Consideration of the long-term, chronic health effects of exposure to cosmetic chemicals linked to cancer, reproductive and developmental harm, endocrine disruption, neurotoxicity and respiratory harm.

8. **Accreditation of 3rd party safety review (Sec. 610).** This section should specifically prohibit the FDA and companies from hiring or relying on safety data generated by the Cosmetic Ingredient Review (CIR), or other third-party safety evaluators that have a financial conflict of interest with the cosmetics industry, for evaluations of ingredient safety.

9. **Manufacturer Ingredient Review.** There appears to be nothing in the discussion draft that requires or defines how the ingredients in a cosmetic product should be substantiated for safety by manufacturers, other than a brief mention in the registration section that companies should provide "an assurance" that the cosmetic products meet the bill's safety standard. The discussion draft should explicitly require cosmetic manufacturers to substantiate the safety of individual chemicals and finished products using the same safety standard as the FDA and specify a minimum battery of safety tests required of cosmetic companies to assess not only acute reactions but long term, chronic health effects when substantiating cosmetic chemicals for safety including but not limited to cancer, reproductive and developmental harm.

10. **Records Review (Sec. 611).** This provision provides the FDA with the authority to inspect records of cosmetic facilities and responsible persons if the agency has reasonable grounds to believe a cosmetic product is adulterated and can cause serious adverse health consequences. The requirements in this provision placed on the FDA to

gain access to the records of facilities suspected of producing adulterated products is too restrictive – specifically this directive: "The FDA is required to provide written notice, at reasonable times, within reasonable limits and in a reasonable manner." If the FDA is dealing with a crisis regarding an adulterated cosmetic product, they need the authority to work address the crisis in an expedited manner. The records review provision is also too limiting in terms of what the FDA can access, given the discussion draft prohibits the FDA from accessing 'recipes or formulas for cosmetics," information the agency would logically need to identify possible sources of adulteration and other matters.

11. **Exemption for certain products and facilities (Sec. 613)**. We are opposed to this section of the discussion draft which would specifically exempt products regulated as over the counter (OTC) drugs from any new regulation created by the proposed legislation. This exemption would mean the safety of cosmetic products regulated as OTC drugs, which are a regular part of many American's daily beauty and hygiene, would not be regulated as strictly as other cosmetic products. As a result of this exemption, public health would be jeopardized because products that make a medical claim such as fluoride toothpaste, antiperspirants, dandruff shampoos, acne medication, sunscreens and SPF moisturizers and make-up, among other things, would be regulated less strictly than similar cosmetic products that do not make a medical claim.

12. **Tighter timelines and fee authority.** We support creating clearer timelines within the bill for the new activities and directives established by this measure, including a maximum timeframe allowed for identifying ingredients to be reviewed for safety and the FDA's issuance of an administrative order regarding their safety determination. We also support the creation of a sliding scale fee structure to help pay for the program.

<u>Federal Preemption:</u>
Protecting against federal preemption of the state's ability to legislate on the issue of cosmetic safety is a core priority of the undersigned organizations and businesses. The states have accomplished important pioneering work in disclosing and regulating unsafe chemical exposures. The states have also long been both the laboratories and sentinels for federal policy reform in this arena. The historical right of the states to self-govern – supported by elected officials on both sides of the aisle – is not something this bill should seek to compromise. The discussion draft should create a strong federal standard that protects everyone from unsafe chemicals in cosmetics and personal care products. At the same time, the states have demonstrated an ongoing commitment to environmental health protections and should retain the right to protect their residents from unsafe chemical exposures. Congress should support federal cosmetic safety reform that builds on that state leadership, not legislate to take it away.

<u>Other Discussion Draft Provisions that we support retaining</u>

1. **Registration & Good Manufacturing Practices:** We support the draft bill's requirement that cosmetic manufacturers register their facilities, products and ingredients with the FDA; and comply with good manufacturing practices.

2. **Protection of Small Businesses:** We support the bill's allowances for small business considerations including FDA technical support and more generous deadlines to help small businesses comply with the law.
3. **Biennial Reporting to Congress and GAO Report.** We support the discussion draft's requirement that the FDA regularly report to congress on ingredients identified for safety review, safety determinations that have been made, number and summary of serious adverse event reports and product categories, number of registered facilities and cosmetic ingredient statements on file, number of facilities inspection, enforcement actions the Secretary has taken and efforts the FDA has taken to reduce animal testing. We also support the requirement that a GAO report be required to provide an in-depth analysis of the success of the expanded FDA authority over cosmetic safety.

We appreciate the Senate HELP Committee's leadership and focus on the need for federal action to improve the safety of beauty and personal care products. We will continue to review and comment on the legislation, and we request that you to take into consideration the recommendations and concerns raised above as you work to revise the Modernization of Cosmetics Regulation Act of 2018.

Thank you in advance for your attention to this important public health, environmental health, children's health and occupational health issue.

Signed,

Beauty & Personal Care Companies
Be Green Bath and Body
Beauty Heroes
Beleza Organica
California Baby
Clarissa International, LLC
Cleure
ClimateMama
Dr. Bronner's
Dr. Whyte Pediatrics
DRIK, LLC
Ecco Bella
Elavo Mundi Solutions, LLC
EO Products
Faces of Astarte Wellness Beauty Salon/Spa
Goddess Beauty LLC
Headwater LLC
Innersense Organic Beauty
Intelligent Nutrients
Jotovi Designs Inc
Just the Goods
Kokomelt
Lena Rose Natural Beauty

My Sisters' Natural
NAIWBE Natural As I Wanna Be
Naturepedic
Neurotically Natural
OSEA
Seriously FAB
Seventh Generation
StormSister Spatique
The Ashkin Group LLC
The Holistic Health Co.
The Honest Company
The Soft Landing
Therapi Honey Skincare
Thinkbaby and Thinksport
Toogga
Trillium Herbal Company
Virgo Terra

Nonprofit Organizations
Alaska Community Action on Toxics
American Sustainable Business Council
Arizona PIRG
Asian Health Services
Blue Green Alliance
Breast Cancer Action
Breast Cancer Prevention Partners
California Clean Water Action
California Communities Against Toxics
California Healthy Nail Salon Collaborative
California PIRG
Campaign for Healthier Solutions
Center for Environmental Health
Citizens' Environmental Coalition
Clean and Healthy New York
Clean Water Action
Colorado PIRG
Communication Workers of America (CWA)
Connecticut Clean Water Action
Connecticut PIRG
Consumer Federation of America
Courage Campaign
Ecology Center
Environmental Health Strategy Center
Florida PIRG
Friends of the Earth
Georgia PIRG

Great Lakes Center for Children's Environmental Health
Green America
Illinois PIRG
Informed Green Solutions
International Center for Technology Assessment
Iowa Breast Cancer Edu-action
Iowa PIRG
Just Transition Alliance
Keep A Breast Foundation
Learning Disabilities Association of Arkansas
Learning Disabilities Association of Illinois
Learning Disabilities Association of Maine
Learning Disabilities Association of Michigan
Learning Disabilities Association of New Jersey
Learning Disabilities Association of South Carolina
Learning Disabilities Association of Tennessee
Los Jardines Institute
Made Safe
Maryland Pesticide Education Network
Maryland PIRG
Massachusetts PIRG
Missouri PIRG
Montana PIRG
National Toxic Encephalopathy Foundation
National Women's Health Network
Natural Resources Defense Council
Necrotizing Enterocolitis Society
New Hampshire PIRG
New Jersey PIRG
New Mexico PIRG
New Voices for Reproductive Justice
Non-Toxic Revolution
North Carolina PIRG
Ohio PIRG
Oregon Environmental Council
Oregon PIRG
Pacoima Beautiful
Rhode Island Clean Water Action
Rhode Island PIRG
Safe and Healthy Connecticut
Safer Chemicals Healthy Families
Safer States
San Francisco Bay Area Physicians for Social Responsibility
Savvy Women's Alliance
Sheet Metal Occupational Health Institute Trust (SMOHIT)
Story of stuff project

Texas PIRG
Toxic Free Future
US Public Interest Research Group (PIRG)
Vermont Conservation Voters
Washington PIRG
Wisconsin PIRG
Women for a Healthy Environment
Women's Voices for the Earth