ENDOCRINE SOCIETY
Hormone Science to Health

April 2, 2019

Representative Frank Pallone Jr.
237 Cannon House Office Building
Washington, DC 20515

Representative John Shimkus
2217 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Representative Shimkus,

The Endocrine Society appreciates the opportunity to provide comments on the discussion draft of the Cosmetic Safety Enhancement Act of 2019. We welcome your work on this important legislative effort to ensure that consumers are adequately protected from hazards associated with exposure to chemicals in personal care products.

Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to the understanding of hormone systems and the clinical care of patients with endocrine diseases and disorders. The Society's membership of over 18,000 includes researchers who are making significant contributions in a new area of science investigating interference with hormonal systems by manufactured chemicals, called endocrine-disrupting chemicals (EDCs). The Society published a comprehensive Scientific Statement on EDCs in 2015, summarizing the current state of the science, research gaps and opportunities, and policy recommendations based on the science.

EDCs in personal care products have been linked to reproductive system disorders, and many EDCs pose greater risks to vulnerable populations, such as pregnant women and young children. These and other potential harms call for improved regulatory review of personal care products.

We are encouraged that the current discussion draft includes many of our priorities related to public health and safety of cosmetics. Below we identify key provisions that should be included in any legislative text to emable the United States Food and Drug Administration (FDA) to more effectively protect the public from EDCs in personal care products.

1. **Cosmetics reform requires a strong safety standard**: Any final legislative text should include a rigorous safety standard for personal care products, Specifically, that the standard should require cosmetic products and ingredients pose a **reasonable certainty of no harm under usual, customary, or intended uses**. We are encouraged by the proposed text for the safety standard in the discussion draft and recommend that this be retained.
2. **FDA must have the authority to review chemicals and set restrictions, including recalls when appropriate**: Consumers expect that products that they purchase have been evaluated and tested for safety. However, many cosmetics ingredients have uncertain safety profiles, and have not been evaluated for interference with endocrine systems. Harms from EDC exposures are linked to diseases including reproductive disorders, neurodevelopmental disorders, cancer, obesity and metabolic syndrome, and others. FDA must have the abilities provided in the discussion draft to review and, when appropriate, restrict the use of chemicals in cosmetics so that they do not contribute to these and other harms. This

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

includes the ability to issue mandatory recalls, should a company fail to remove a dangerous product from the market. We note that the European Union, Canada, and other governments have placed restrictions on many chemicals in cosmetics because of endocrine disrupting properties, and the FDA should be encouraged to review these and other regulatory assessments to identify chemicals for review.

3. **Vulnerable populations should be protected**: We strongly support the provisions in the discussion draft that take vulnerable populations into consideration, such as specific requirements for labelling and/or warnings for vulnerable populations. As we previously mentioned, many EDCs pose greater risks to vulnerable populations, such as infants with developing hormonal systems. It is therefore important for FDA to carefully consider the potential for harm to these and other vulnerable populations.
4. **FDA should have the resources and information it needs to conduct scientific reviews**: The Endocrine Society strongly supports the proposed fee-based structures in the discussion draft to give FDA the necessary resources to conduct chemical reviews. We also support provisions in the discussion draft aimed at ensuring that FDA is able to obtain information from manufacturers to conduct thorough reviews, including information about the ranges of ingredient concentrations to provide accurate exposure estimates.
5. **Consumers should have access to information about the chemicals that they are exposed to**: The Endocrine Society supports the provision in the discussion draft regarding the ability of consumers to obtain ingredient informaiton, including fragrance and flavor ingredients, through a publicly accessible toll-free number. This information is critical to patients and healthcare providers in the event of adverse reactions or uncertainty regarding the safety of specific ingredients.

The Endocrine Society is appreciative of your work in this important area. We look forward to working with you to craft effective legislation that protects the public from harms due to dangerous chemicals in cosmetics. If we can be of any assistance, please do not hesitate to reach out to us by contacting Joseph Laakso, Director of Science Policy at jlaakso@endocrine.org.

Sincerely,

E. Dale Abel MD PhD
President
Endocrine Society