June 11, 2019

The Honorable Frank Pallone
Chairman
House Energy & Commerce Committee
2107 Rayburn HOB
Washington, DC 20515

The Honorable John Shimkus
Member
House Energy & Commerce Committee
2217 Rayburn HOB
Washington, DC 20515

Dear Chairman Pallone and Representative Shimkus:

We, the undersigned scientific, medical, and professional societies and public health organizations write to thank you for your efforts to modernize the Food and Drug Administration's authority over the regulation of cosmetics. The links between repeated exposure to ingredients commonly used in cosmetics and long-term health impacts to the reproductive, developmental, and endocrine systems are of increasing concern to the medical and scientific community.[1][2] Some ingredients in cosmetics have even been linked to cancer.[3] We strongly support efforts to bolster FDA's authority to study these chronic risks and regulate these ingredients accordingly to better fulfill the agency's mission to protect public health.

A critical piece of any reform legislation is a mandatory review program that requires FDA to systematically assess the safety of cosmetic ingredients and nonfunctional constituents and regulate consistent with its safety findings. When evaluating safety, we believe it is important that FDA find that there is *a reasonable certainty* that the ingredient or nonfunctional constituent *will cause no harm*. The "reasonable certainty of no harm" standard is a robust, well-understood safety standard that FDA and other agencies have used for more than 60 years to study and regulate long-term risks from repeat-use exposure from food additives, color additives, animal drugs, and pesticide residues on food.

Under current law, FDA may only take action on a cosmetic when it finds that the cosmetic is "adulterated"[4] or "misbranded."[5] Section 601(a) of the Federal Food Drug & Cosmetics Act (21 U.S.C. § 361(a)) states that a cosmetic is deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual."[6] A cosmetic is also adulterated under the FDCA if packed in unsanitary conditions that

[1] https://www.ncbi.nlm.nih.gov/pubmed/22398195
[2] https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2633254
[3] Cal. Dep't of Pub. Health, Cal. Safe Cosmetics Program, Current Data Summary, https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/CSCP/Pages/SummaryData.aspx (last accessed May, 5, 2019). The California Safe Cosmetics Act of 2005 requires cosmetic manufacturers to disclose to the California Department of Public Health all products containing ingredients known or suspected to cause cancer, birth defects or other reproductive toxicity as determined by certain authoritative scientific bodies, including the Environmental Protection Agency, the National Toxicology Program and the International Agency for Research on Cancer.
[4] 21 U.S.C. § 361.
[5] 21 U.S.C. § 362.
[6] 21 U.S.C. § 361.

may render it "injurious to health" or its container is composed in whole or part of any poisonous or deleterious substance that may render it "injurious to health."[7]

In practice, FDA has only used this authority to find a cosmetic "adulterated" based on chronic risks from certain ingredients a handful of times.[8] In March, after testing samples of cosmetics purchased from Claire's and Justice were found to be contaminated with asbestos, FDA lamented its limited authority over cosmetics, stating, "when it comes to cosmetics, our authority hasn't changed in many years even as the industry has undergone rapid evolution."[9]

By contrast, the FDA scientists who review the safety of food additives, color additives, and new animal drugs, as well as the Environmental Protection Agency scientists who set tolerances for pesticide residues apply the "reasonable certainty of no harm" standard to assess chronic risks for cancer, reproductive and developmental harms, endocrine disruption, and neurotoxicity everyday. Just last year, FDA revoked approval for lead acetate as a color additive in hair dye because the "new data available since lead acetate was permanently listed demonstrate that there is no longer a reasonable certainty of no harm."

Given the FDA's 60-plus year track record applying the "reasonable certainty of no harm standard" to long-term risks from repeated exposure to chemicals of concern, we strongly believe it is the most appropriate safety standard to apply to the safety of cosmetics. We appreciate the inclusion of this standard in your most recent Discussion Draft and urge you to include it in any cosmetics legislation introduced in the 116th Congress.

Sincerely,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

Breast Cancer Prevention Partners

Endocrine Society

The Gerontological Society of America

National Alliance for Hispanic Health

National Women's Health Network

Society of Toxicology

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[7] 21 U.S.C. § 361(c)-(d).

[8] https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics

[9] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and