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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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August 22, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

I am writing to request that the Energy and Commerce Committee hold a hearing to examine the current regulatory framework for cosmetics. Such a hearing would allow the Committee to better understand how the regulatory landscape has changed since the U.S. Food and Drug Administration (FDA) was first granted authority over cosmetics in 1938, and what additional authorities FDA needs to ensure cosmetic products are safe for the millions of Americans that use these products every day.

Currently, FDA has limited authority to regulate cosmetic products under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act prohibits a manufacturer from marketing adulterated or misbranded cosmetics, which requires that a cosmetic product be safe when used according to the instructions on the label. However, FDA's authority over cosmetics differs significantly from the agency's authority over other regulated products in that FDA lacks the authority to review a cosmetic product premarket; therefore, FDA does not verify the safety of a product before it is sold to consumers. Instead, the companies or individuals that manufacture or market cosmetics are responsible for testing and verifying the safety of their products, and these entities are not required to share safety information with FDA. FDA also does not have authority to require that a cosmetic manufacturer register with the agency, so FDA often does not know what entities are manufacturing or marketing cosmetic products, or how these entities make cosmetic safety determinations.

Another limitation of the current cosmetic regulatory framework is that cosmetic manufacturers have no obligation to notify FDA if they receive adverse event reports from consumers. And even if FDA becomes aware of adverse events associated with a cosmetic product, the agency lacks the authority to require that a manufacturer recall a product. The only

way for FDA to remove a potentially unsafe product from the market is to request that a company initiate a voluntary recall or work with the Department of Justice to initiate a product seizure. This differs from FDA's authority over any other product the agency regulates.

One recent example that highlights deficiencies in the current cosmetic regulatory regime involves Guthy-Renker, LLC's hair care products, specifically WEN by Chaz Dean cleansing conditioners. On July 19, 2016, FDA issued a safety alert stating that it was investigating reports of hair loss, breakage, balding, itching, and rash associated with WEN's cleansing conditioners. As of July 7, 2016, FDA has received 127 adverse event reports from consumers, the largest number of reports ever received for a cosmetic hair cleansing product.[1] Even more troubling is that, during FDA's investigation of the facilities that manufacture and distribute WEN cleansing conditioners, FDA discovered that since 2008, consumers filed more than 21,000 complaints with the company about these products.[2] Under current law, Guthy-Renker was not required at any time to submit these complaints to the agency. As of July 2016, more than 200 women in 40 states joined a class action lawsuit against WEN by Chaz Dean and Guthy-Renker, LLC, claiming extreme hair loss and damage after using the products as instructed.[3] Despite these complaints, WEN cleansing conditioners remain on the market as FDA continues its investigation.[4]

The last time this committee held a hearing on cosmetic regulation was on March 27, 2012. At this hearing, titled "Examining the Current State of Cosmetics," we heard from a wide variety of stakeholders, including FDA, cosmetic manufacturers and suppliers, a state health department employee, and a cosmetic trade association. From FDA we heard of the challenges the agency faced when trying to ensure the safety of products, due to the increasing number of cosmetics on the market. FDA testified that, in 2012, estimated sales of cosmetics products in the United States ranged from $54 to $60 billion.[5] FDA also shared the challenges of regulating

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[1] U.S. Food and Drug Administration, *WEN by Chaz Dean Cleansing Conditioners: FDA Statement - Investigation of Adverse Event Reports* (July 19, 2016) (www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511890.htm).

[2] U.S. Food and Drug Administration, *FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners* (Aug. 11, 2016) (www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm511631.htm).

[3] Consumer Affairs, *Feds examine complaints about WEN by Chaz Dean hair treatments* (July 20, 2016) (www.consumeraffairs.com/news/feds-examine-complaints-about-wen-by-chaz-dean-hair-treatments-072016.html).

[4] WEN by Chaz Dean website (www.wen.com/cart?lang=default&grcid=core) (accessed Aug. 2, 2016) (WEN cleansing conditioners are also currently available through several online retailers, including Amazon, Sephora, and QVC).

[5] House Committee on Energy and Commerce, Testimony of Michael Landa, former Director of FDA's Center for Food Safety and Applied Nutrition, *Hearing on Examining the*

an increasingly global industry in which so many products are imported into the United States, often from countries that have different regulatory systems and standards. Lastly, FDA shared the need for legislative authority to assess cosmetic user fees in order to provide the agency with adequate resources to ensure cosmetics marketed to U.S. consumers are safe.

During this same hearing, we heard support for the effort to modernize FDA's regulatory framework from cosmetic trade associations to help ensure that U.S. cosmetics remain some of the safest in the world.[6] Lastly, we heard that there is growing public concern about the safety of cosmetic products, particularly regarding the lack of information about cosmetic product ingredients and long-term effects of cosmetic use.[7] Given that four years have passed since this hearing and we have yet to pass legislation to address any of the issues raised, we owe it to the American public to revisit this issue and determine how we, as members of Congress, can fix systematic failures that allow consumer harm, such as that seen in the case of WEN cleansing conditioners, to continue.

Reform of our country's cosmetics regulatory system is long overdue. This committee, as the committee with jurisdiction over cosmetic regulation, should examine the existing framework and determine what improvements are necessary. We owe it to American consumers to do all we can to ensure we have a robust cosmetic regulatory system that ensures the safety of the cosmetic products that Americans purchase and use each day. I urge you to hold a hearing on this topic when Congress returns in September, and hope we can work together to bring cosmetic regulation into the 21st Century.

Sincerely,

Frank Pallone, Jr.

Frank Pallone, Jr.
Ranking Member

Current State of Cosmetics, 112th Cong. (Mar. 27, 2012) (energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-LandaM-20120327.pdf).

[6] House Committee on Energy and Commerce, Testimony of Peter Barton Hutt, Senior Counsel at Covington and Burling, *Hearing on Examining the Current State of Cosmetics*, 112th Cong. (Mar. 27, 2012) (energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-HuttP-20120327.pdf).

[7] House Committee on Energy and Commerce, Testimony of Dr. Michael DiBartolomeis, California Department of Public Health, *Hearing on Examining the Current State of Cosmetics*, 112th Cong. (Mar. 27, 2012) (energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/Health/20120327/HHRG-112-IF14-WState-DiBartolomeis-20120327.pdf).

cc: The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce