Nation's Cosmetic Companies Call for Enhanced FDA Role in Ensuring Safety of Personal Care Products

For Immediate Release:
April 19, 2012
Groundbreaking Legislation Would Advance Federal Oversight and Modernize Regulations

WASHINGTON, D.C. (April 19, 2012) – The nation's cosmetic industry announced today its support for groundbreaking legislation to strengthen and modernize regulatory oversight of the industry and to create a greater role for the U.S. Food and Drug Administration (FDA) in assessing the safety of personal care products.

Introduced by Representative Leonard Lance (R-NJ), the "Cosmetic Safety Amendments Act of 2012," H.R. 4395, will modernize federal oversight of cosmetics and personal care products, currently one of the safest product categories regulated by the FDA. H.R. 4395 builds on that strong record. The proposal has the full support of the Personal Care Products Council and the Safe Cosmetics Alliance, which have consistently advocated for an updated, enhanced and transparent regulatory framework for FDA.

"FDA regulation of cosmetics has protected the public for decades, and this landmark legislation will enhance protections for millions of American consumers," said Lezlee Westine, the Council's president and chief executive officer. "Cosmetics companies recognize the need for a modern regulatory process that keeps pace with product innovation, as well as the demand for transparency. The Council applauds Congressman Lance for introducing this bill and will work to help gain bipartisan support for its passage."

The cosmetic and personal care industry employs 8.2 million people, directly or indirectly, in the United States. The industry has an estimated $60 billion in annual American retail sales and is a net exporter. Small businesses with 50 or fewer employees make up 92% of the industry and women represent 66% of its workforce.

"Everyone agrees that we need to update the regulation of personal care products," said Representative Lance. "This bill will continue to advance consumer safety and provide a regulatory framework that furthers growth and innovation for American cosmetics manufacturers and small businesses."

H.R. 4395 calls for increased reporting and transparency by the industry and enhanced regulatory oversight without further straining taxpayer resources and damaging small and medium-sized businesses' ability to compete globally and create new manufacturing jobs in the U.S.

The legislation aims to create formal processes for the FDA to review ingredients for safety, set safety levels for trace impurities, create national uniformity for cosmetics regulations, review all safety determinations made by the Cosmetic Ingredient Review (CIR) Expert Panel and establish industry-wide "Good Manufacturing Practices." CIR is an independent panel of scientific and medical experts that assesses the safety of cosmetic ingredients used in the U.S. In addition, under

the new legislation, the voluntary registration programs for facilities and products would become mandatory, as would the reporting of any serious and unexpected adverse events.

H.R. 4395 builds upon portions of legislation originally introduced by Congressman John Dingell (D-MI) known as "The FDA Globalization Act of 2008." Congressman Frank Pallone (D-NJ) along with Congressman Dingell recently introduced legislation that has similar provisions to H.R. 4395.

"Our industry is built on the trusted relationships we have established with consumers. We have always believed in going above and beyond the requirements of the current law," said Westine. "This critical legislation provides a roadmap for a contemporary approach that includes a more engaged and transparent federal regulatory role."

"We look forward to working with Congressman Lance on this legislation," said Westine. "We also look forward to working on a bipartisan basis with Congressmen Pallone and Dingell on legislation that updates FDA regulation of cosmetics and enhances consumer protections."

Strong federal safety requirements currently govern cosmetics and personal care products sold in the U.S. The safety of cosmetic and personal care products in the U.S. is overseen by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act), which requires that all cosmetics be substantiated for safety before they are marketed, contain no prohibited ingredients, and that all labeling and packaging be in compliance with U.S. regulations. Under the FD&C Act it is a crime to market an unsafe cosmetic product.

The new legislation introduced by Congressman Lance makes several key improvements to current law including:

(1) Enhanced FDA Registration. It requires that personal care products manufacturers who market their products in the United States comply with the following:
Register all facilities where those products are manufactured.
File product ingredient reports disclosing ingredients used, consistent with current guidelines.
Report any serious unexpected adverse event with a product experienced by a consumer.

(2) New Process to Set Safety Levels for Trace Constituents. When requested or on its own initiative, FDA would be required to establish safe levels for trace constituents in cosmetic ingredients and products.

(3) New FDA Ingredient Review Process. Once a request has been made, or FDA determines review is warranted, the agency would be required to make a determination about the safety of any ingredient intended for use in a personal care product and set safe use levels for such ingredient on a specified timetable.

(4) New FDA Oversight of CIR Findings. FDA would be required to review current and future findings on the safety of cosmetic ingredients by the Cosmetic Ingredient Review (CIR) Expert Panel and determine if these findings are correct. If there are instances in which it determines a CIR finding is unsupported, FDA would determine by guidance or regulations if, or under what conditions, the ingredient can be used safely in cosmetic products.

(5) FDA-Issued Good Manufacturing Practices. FDA would establish industry-wide “Good Manufacturing Practices” requirements.

(6) National Uniformity. FDA’s new regulatory authority would preempt similar state legislation for cosmetics and personal care products.

For more information about the Safe Cosmetics Alliance, a coalition that includes the Independent Manufacturers and Distributors (ICMAD), Professional Beauty Association (PBA), Direct Selling Association (DSA), International Fragrance Association (IFRA) and the Personal Care Products Council, visit www.safecosmeticsalliance.org.

For more information about cosmetic and personal care products, visit www.cosmeticsinfo.org.

Based in Washington, D.C., the Personal Care Products Council is the leading national trade association representing the global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on every day, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

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