

**Prepared Written Testimony of Pamela G. Bailey**

**Chief Executive Officer and President**

**The Personal Care Products Council**

**UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON  
ENERGY AND COMMERCE**

**MAY 14<sup>th</sup>, 2008**

Chairman Pallone, Ranking Member Deal, and distinguished Members of the Committee:

I am here today on behalf of the Personal Care Products Council, formerly the Cosmetic, Toiletry, and Fragrance Association. I appreciate the opportunity to appear before you to discuss the long-standing commitment to safety that personal care product companies have demonstrated and the resulting strong record of safety for our products.

Founded in 1894 and based in Washington, D.C., the Council is the leading national trade association representing the global cosmetic and personal care products industry. We represent over 600 member companies, including leading U.S. and global brands like L'Oreal, Procter & Gamble, Mary Kay, Avon, The Dial Corporation, Johnson & Johnson, Unilever, Estee Lauder, Revlon, and several hundred small businesses with annual revenue under ten million dollars.

From sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, our companies manufacture, supply, and distribute 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 everyday, personal care products companies are global leaders committed to product safety, quality, and innovation.

We would like to state upfront that we appreciate and support the goal of this legislation and the cosmetic section – to ensure that FDA has the authority to provide strong oversight so that American consumers can be assured that imported products are safe.

Consumer safety has always been the number one priority of our cosmetics and personal care products companies. The most important law pertaining to the safety of cosmetics marketed in the United States is the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, as currently amended.

Under this law, the organizing principles of cosmetic safety were established. There is a strong, existing regulatory framework. Under this law, it is a crime to market an unsafe cosmetic product. Let me restate that: it is a crime to market an unsafe cosmetic product. Cosmetic companies are responsible for substantiating the safety of their products and the individual ingredients before marketing. The FDA's responsibility is to provide regulatory oversight through the creation and enforcement of safety and labeling regulations that hold industry accountable and to conduct post-market surveillance to determine whether a cosmetic is in violation of the FD&C Act and should be removed from the marketplace. In addition, FDA collects samples for examination and analysis as part of its plant inspections, inspects imported goods, and conducts follow-up to

complaints of adverse reactions. FDA may also conduct research on cosmetic products and ingredients to address safety concerns.

It is also important to note that under the FD&C Act, any cosmetic that contains an active ingredient - - such as sunscreens, anti-caries toothpaste, mouthwash, antiperspirants and anti-dandruff shampoo - - is also categorized as a drug and as such is regulated under the stricter FDA drug safety regime. It is also significant that color additives used in cosmetics are carved out under the FD&C Act for a strict system of FDA pre-market approval.

Cosmetics products imported into the U.S. are subject to the same substantive standards as those produced in the U.S., and face an even higher regulatory threshold upon entry into the U.S., in that an “appearance” of adulteration or misbranding may subject them to detention at the border. They must be safe and contain no prohibited ingredients, and all labeling and packaging must be in compliance with U.S. regulations. All colors must be listed and pre-approved by FDA, and a number of color additives must be batch certified by FDA. If the product has an intended use that causes it to be considered an over-the-counter (OTC) drug, it must comply with the regulations for drugs, including establishment registration and drug listing.

The issue of product safety in a global marketplace is not only a matter of law for our members, but it is the primary commitment for each of them and for our trade association. That’s why our companies invest substantial resources every year in

scientific research and safety processes to ensure product safety. They work diligently with thousands of expert chemists, toxicologists, and biologists to evaluate the safety of cosmetic products before they go to market.

In addition to their own individual efforts, for nearly forty years our companies have invested millions of dollars through our trade association in programs to enhance and supplement the safety commitments of each individual company by providing additional safety and technical resources and information through initiatives such as:

**The FDA Company Registration Program (VCRP)** through which FDA collects information on manufacturers, packers, and distributors of cosmetic products in commercial distribution in the U.S. **The Cosmetic Ingredient Review (CIR)** – an independent expert panel of scientists and physicians that evaluate safety data for the most commonly-used cosmetic ingredients. **The Cosmetic Ingredient Dictionary** that has been cited by the FDA as the primary source of ingredient names for the FDA regulation requiring cosmetic ingredient labeling. **Technical Guidelines** for the industry that provide information on microbiological testing, quality assurance, and safety testing.

**A Consumer Commitment Code** that requires our member companies to go beyond the requirements of the law by agreeing to open their scientific data and information to FDA scrutiny; to report to FDA serious and unexpected adverse consumer experiences with a cosmetic product; and to register their manufacturing establishments and thousands of formulas with the FDA Registration Program.

**The Establishment of International Consumer Safety Standards** through the International Organization for Standardization (ISO) program, and a **Global Harmonization of Regulations process called ICCR**, an official dialogue of international cosmetics regulatory authorities joined by the cosmetics industry trade associations.

At the direction of our Board, the Council also created an **Import Safety Committee** last year to benchmark our industry's best practices and policy objectives with respect to import safety with the goal of developing additional industry guidelines.

In addition to the numerous industry regulatory programs in place, the Personal Care Products Council also developed a **Consumer Information Website, CosmeticsInfo.org**. The site, launched in 2007, was created to provide consumers with easy access to in-depth, scientifically-based information about cosmetic and personal care products and ingredients.

The result of these manufacturer safety practices and voluntary initiatives under a framework of Federal law has been an outstanding safety record that has been commended by previous FDA Commissioners.. Cosmetics and personal care products are the safest category of products regulated by the FDA.

We recognize, just as the Committee has, that ours is now a global industry with products and ingredients manufactured and sourced across the world.

In this global era, we agree with the Committee that FDA needs basic information about the safety of products and where and how they are manufactured. That's why three years ago, when we wrote our Consumer Commitment Code, which took effect in January 2007, we required member companies signing on to the Code to both register cosmetic facilities and to report serious and unexpected adverse reactions to the FDA.

We are proud that in just the first sixteen months of its implementation, eighty (80) percent of all U.S. annual sales are covered by our board member companies who have signed this Code and that all have registered their manufacturing facilities and products with the FDA.

We are proud that a majority of our members have signed the Consumer Commitment Code, and that those who have signed are required to report serious and unexpected adverse events.

We are proud that the industry has helped craft standards for Good Manufacturing Practices that are now being adopted by the countries that lead international standard setting.

We are proud too of our work to put key scientific safety information in the hands of consumers through our new consumer information site. But we want to do more.

We have a multi-year plan to enhance and expand the CIR processes, adding expertise, expanding capacity for ingredient safety reviews, and increasing transparency.

The Committee and the draft bill have challenged us to take the next step. Exactly how that is done is important. We have been working with the bipartisan staff to provide technical details on the draft's regulatory provisions, and we appreciate this opportunity.

Unfortunately, while the industry has consistently expanded its voluntary initiatives to enhance consumer safety, FDA resources allocated for cosmetics oversight have declined. We understand that FDA prioritizes its scarce budget resources and cosmetics are the lowest risk category, yet we believe the most effective way to enhance cosmetic safety is to provide additional federal resources for FDA. FDA as the “tough cop on the beat” is the best preventative measure for companies who might be tempted to not do the right thing and to help hold all companies accountable.

In 1974, FDA's cosmetics program had 87 full-time equivalents (FTEs) – that number was down to 18 last year. The budget for cosmetics at FDA in 1974 was \$2.7 million, a real dollar equivalent of \$14.5 million today. FDA's actual cosmetic budget for 2007 was only \$3.5 million.

Because we support a strong and vigilant FDA, in 2007, we actively lobbied on Capitol Hill to secure additional funding for the Office of Cosmetics and Colors, and these efforts were a success. This past Fall, the House of Representatives led the way by voting to add \$2 million to the FDA cosmetics budget, a number that was subsequently lowered to \$1 million in conference, leading to a current budget of \$4.5 million. This is still too little. In 2008, we will continue to lobby for an additional \$1 million increase in funding.

Mr. Chairman, I want to close with a note on the registration and import fees. The Committee knows that our industry has never been subject to fees. This is a fundamentally new issue for us. Our member companies have been meeting and working around the clock to address this issue, but today, we neither oppose nor support the proposals in the draft bill. We need additional time to address this and other issues.

Chairman Pallone, Ranking Member Deal, and distinguished Members of the Committee, thank you again for the opportunity to work with the Committee staff on this legislation. Our industry has always put safety first. We have done that by always being willing to take the next step, and we look forward to working with you on this next step: to continue to ensure the safety of consumers in America.

Thank you.

## **APPENDIX A: Personal Care Products Council Consumer Safety**

### Initiatives

- **FDA Company Registration Program (VCRP):** In 1974, when what was then CTFA recognized the FDA’s need to have basic information about cosmetic manufacturing and products, this trade association petitioned the agency to establish regulations for the voluntary submission of establishment registration, product listing, and adverse event reporting. Under the Voluntary Cosmetic Registration Program (VCRP), FDA collects information on manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the U.S., including: company and parent company names, type of product, brand name of product, ingredient and chemical name, discontinuance of a product, and other key data. As noted by FDA, “[t]he VCRP helps FDA in its mission to protect consumers, while also helping cosmetic manufacturers and distributors make informed decisions.” In this way, each company is telling FDA where they are located and what products they make.

Based on information received through the Voluntary Cosmetic Registration Program, FDA can determine if a cosmetic ingredient being used is harmful and

should be removed from product use and then notify the manufacturers and distributors of affected products by using the VCRP database. The VCRP applies to all cosmetic products being sold to consumers in the United States.

Participation in this important program is a key component of the Personal Care Products Council Consumer Commitment Code. Every member of the Personal Care Products Council's Board of Directors has signed onto the Council's Consumer Commitment Code, instituted last year, which requires complete participation in the FDA registry program. Together, these companies' sales volume represents more than 80 percent of the U.S. market and 94 percent of Council member sales.

The Voluntary Cosmetic Registration Program also supports the independent safety evaluation of cosmetic ingredients. Information from the VCRP database assists the CIR in determining its priorities for ingredient safety review.

Two years ago, the Council was a vocal advocate for updating the program to an electronic filing system in order to achieve a more efficient registration process.

- **Cosmetic Ingredient Review (CIR):** In 1976, our trade association founded the CIR – the Cosmetic Ingredient Review program – to evaluate safety data for the most commonly-used cosmetic ingredients. CIR helps manufacturers meet their obligations to ensure that each ingredient used in a cosmetic and each finished

cosmetic product is safe before it is marketed. Members of the CIR expert panel are seven leading academic scientists and physicians who must meet the same conflict of interest requirements as special non-government advisory panels to FDA. They represent the disciplines of dermatology, pharmacology, chemistry, toxicology and oncology. The panel includes non-voting participation by an industry representative, an FDA liaison for the Office of Cosmetics and Colors, and a consumer representative from the Consumer Federation of America.

We are proud that both FDA and the Consumer Federation of America have been part of the CIR comment and discussion process from the beginning. For 30 years, this independent, non-profit panel has contributed to product safety by evaluating more than 1,300 ingredients and publishing their findings in peer-reviewed scientific literature. Final reports are also transmitted to the FDA Commissioner and the Panel conclusions are available on the CIR website for the public.

While the CIR is independent from any association with the industry, it is funded entirely by the cosmetic industry and does not place a resource burden on FDA. The industry is in the process of expanding the activities of this effort by possibly doubling its investment in CIR to increase the output of the expert panel.

As we move forward in 2008, the Council has outlined a multi-year action plan to enhance and expand on CIR because we believe firmly that the regulatory process

is fluid and ongoing and requires constant updating and improvements in order to be most effective. We plan to add additional experts to the Panel, increase greater capacity for staff, and expand the scope of ingredient evaluation.

- **Cosmetic Ingredient Dictionary:** The Council established in 1973, and today still maintains, an International Cosmetic Ingredient Dictionary (ICID) that makes ingredient labeling meaningful. The dictionary has been cited by the FDA as the primary source of ingredient names for the FDA regulation requiring cosmetic ingredient labeling, and has become the principal reference for ingredient names in efforts to harmonize labeling requirements between the EU, US, Canada, Australia and other countries.

The dictionary, published by the Council through an international committee of experts, provides a comprehensive listing of ingredients that might be used in cosmetic and personal care products and the names by which they must be declared on product labels. The dictionary is an important resource prepared for the benefit of consumers, the FDA, and manufacturers. The combined dictionary and handbook contains more than 14,000 International Nomenclature Cosmetic Ingredient (INCI) labeling names for the United States, the European Union, and other countries. These are cross-referenced to nearly 60,000 trade and technical names and 3,000 suppliers from 91 countries.

The ICID is an industry-sponsored effort to establish an orderly process for the designation of ingredients and has become the primary source used for selecting

acceptable ingredient names for label declaration. The need for uniformity in cosmetic ingredient nomenclature has been recognized in countries around the world. There are numerous benefits to a global system of labeling names for cosmetic ingredients, including the consistency and transparency provided to consumers as ingredients are identified by a single labeling name regardless of the national origin of the product. Scientists and dermatologists are also ensured that information will be referenced by a uniform name, eliminating the possibility of confusion or misidentification from the use of multiple names for the same material.

- **Technical Guidelines:** Our trade association in 1969 established Technical Guidelines for the industry to help assure safe, high-quality products. These guidelines provide information on microbiological testing, quality assurance and safety testing. The publication of Technical Guidelines to assist domestic and foreign manufacturers in the development and marketing of safe products has been an important association activity for more than 35 years.
- **Consumer Commitment Code (Established January 2007):** The Council's Board of Directors resolved two years ago to establish the Consumer Commitment Code as a key industry program supporting product safety. Put into effect January of 2007, the Code requires our member companies who have signed the Code to formalize and strengthen the product safety practices that are followed for most personal care product companies. Under the Code, companies must go beyond the requirements of the law by agreeing to open their scientific

data and information to FDA scrutiny; to report to FDA serious and unexpected adverse consumer experiences with a cosmetic product; and make a positive commitment to register their manufacturing establishments and thousands of formulas with the FDA voluntary registration program.

All members of the Council's Board of Directors have signed the Code on behalf of their companies. Together, their companies' sales volume represents more than 80 percent of the U.S. market and 93 percent of Council member sales.

- **Establishment of International Standards:** Our companies have been in the forefront of efforts to develop international safety standards through the International Organization for Standardization (ISO) program. In this capacity, the Personal Care Products Council has taken the lead in representing U.S. industry. ISO has developed or is working on standards for microbiology test methods, product labeling, analytical test methods for contaminants, Good Manufacturing Practices, and sunscreen test methods. These guidelines offer organizational and practical advice on the management of the human, technical, and administrative factors affecting product quality of cosmetics with a global view.
- **Global Harmonization of Regulations & ICCR (Initiated 2007):** In response to the globalization of our marketplace and divergent safety standards worldwide, in 2007, the Council proposed that global regulators launch and FDA participate

in the International Cooperation on Cosmetics Regulation (ICCR), which held its first meeting in Brussels this past September. ICCR is an official dialogue of cosmetics regulatory authorities from Canada, European Union, Japan and the U.S. joined by the cosmetics industry trade associations Colipa (Europe), CCTFA (Canada), JCIA (Japan) and the CTFA (United States).

The ICCR is actively working to create consistent global safety and regulatory standards especially in the areas of ingredient labeling, nanotechnology and alternatives to animal testing. Taking advantage of work already accomplished by industry and global regulatory authorities to establish a global Good Manufacturing Practices (GMP) standard under ISO, one of the first ICCR work items was to agree that all participating regulating authorities would adopt the ISO GMP standards for cosmetics. This would mean that companies operating in ICCR markets will have a consistent reference on GMPs. The Council has urged FDA to issue guidance on cosmetics GMPs in the U.S., that refer to these ISO standards, consistent with their ICCR agreement.

- **Import Safety Committee:** Established in 2007, at the direction of the Board, to benchmark our industry's best practices and policy objectives with respect to import safety. This Committee is made up of senior industry representatives with responsibility for global quality assurance, supply chain management, purchasing and other disciplines. We are aggressively reviewing current industry procedures

around assuring the safety of the total supply chain and identifying best practices with the express goal of developing additional industry guidelines and practice.

We intend for these guidelines to serve as the basis for new programs to educate and to assist smaller and medium sized companies. As we move forward, these efforts will also give us the tools to determine the need for any additional measures, such as third party certifications, international cooperation or other steps that will allow us to further enhance our import safety practices.

- **In-Depth Scientific Consumer Information Website (Launched December 2007):** In the fall of 2007, the Council completed an intensive two year effort and launched our consumer information website, CosmeticsInfo.org, which we created to provide consumers with easy access to in-depth, scientifically-based information about personal care products. Linked to government sites, CosmeticsInfo.Org provides information on 13 personal care product categories and more than 1,500 ingredients, representing the majority of ingredients most commonly used in personal care products today.

The information provided on the site also shows consumers how to read cosmetic labels, how cosmetics are regulated, and the complex, multi-step process companies use to assess the safety of cosmetic ingredients and finished products. The site will be continually updated and expanded to provide consumers with latest information available on personal care products and ingredients.