DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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STATEMENT

OF

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"EXAMINING THE CURRENT STATE OF COSMETICS"

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INTRODUCTION

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Michael Landa, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services. I am pleased to be here today to discuss FDA's oversight of cosmetics. Every day across the country, Americans—men, women, and children—use a wide variety of cosmetic products, including skin moisturizers, shampoos, perfumes, lipsticks, nail polishes, eye and face make-up, hair colors, and deodorants. These consumers expect their cosmetics—and the wide variety of individual ingredients in these products—to be safe. FDA plays a critical role in ensuring that the nation's cosmetics are among the safest in the world.

In my testimony today, I will describe FDA's current authorities and activities to oversee the safety of cosmetics, the challenges we face due to changes in the industry and the increasingly global marketplace, and the new authorities the Administration is seeking to strengthen FDA's regulatory oversight of cosmetics.

CURRENT AUTHORITIES AND ACTIVITIES RELATED TO COSMETIC SAFETY

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a cosmetic as an "article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting effectiveness, or altering the appearance." The definition also includes articles intended for use as a component of any such articles. Cosmetics firms are responsible for substantiating the safety

of their products and ingredients before marketing. However, they are not required to submit safety substantiation data to the Agency, nor to make it available to the Agency. Under the FD&C Act, cosmetic products and ingredients (with the exception of color additives) are not subject to FDA premarket approval or premarket notification.

In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products due to safety concerns. Some examples are chloroform, methylene chloride, and mercury-containing compounds. If manufacturers do not remove dangerous products from the market once a safety concern emerges, the Agency can pursue enforcement actions against violative products or against firms or individuals who violate the law.

Regulations are in place that specify the labeling requirements for cosmetics. These requirements include:

- An identity statement indicating the nature and use of the product (for example, “shampoo” or “lip gloss”);
- The name and place of business of the manufacturer, packer, or distributor;

- A net quantity of contents statement in terms of weight, measure, or numerical count (e.g., “net wt. 4 oz.”) to inform consumers of the quantity of the cosmetic in the package;
- Material facts about the product and its use (for example, directions for safe use, if a product could be unsafe if used incorrectly);
- Warning and caution statements for products that are required to bear such statements by the FD&C Act and FDA’s regulations (for example, coal tar hair dyes); and
- A list of ingredients, in descending order of predominance.

Cosmetic product labels do not need to provide information on how consumers and health care professionals can report adverse events to the manufacturer, packer, or distributor. However, FDA has long encouraged cosmetics manufacturers and distributors to report adverse events voluntarily.

FDA also encourages companies to register their establishments through the Voluntary Cosmetic Registration Program (VCRP) and file cosmetic product ingredient statements with FDA; however, there is no requirement in the FD&C Act for firms to do either. The Agency established the VCRP and the cosmetic product ingredient statement program to gain more information about cosmetics that are being manufactured and marketed to consumers in the United States. The VCRP currently has almost 1,600 domestic and foreign registered cosmetics establishments, and cosmetic product ingredient statements have been filed for over

39,000 products; however, we estimate that only one-third of cosmetics manufacturers voluntarily file cosmetic product ingredient statements for their products with FDA.

FDA participates in the Cosmetic Ingredient Review (CIR) panel, which was established in 1976 by industry, with the support of FDA and the Consumer Federation of America (CFA). The panel consists of academic experts in the fields of dermatology, pharmacology, toxicology, and chemistry, who are voting members of the panel, as well as three non-voting, liaison representatives from FDA, CFA, and industry. The purpose of CIR is to provide expert review of cosmetic ingredients having potential safety issues. Substances for review are chosen based on frequency of use and safety concerns raised by industry, FDA, or other regulatory bodies within the United States or abroad. Data is compiled by the CIR staff and forwarded to panel members for review and discussion at quarterly meetings, which are open to consumers, industry and the press.

CHALLENGES

During the past several years, Americans have seen a dramatic increase in the numbers and types of cosmetic products on the market. Over 8 billion personal care products, which include primarily cosmetics but also some over-the-counter (OTC) drugs and some products regulated by the Consumer Product Safety Commission, are sold annually in the United States. Estimates of annual U.S. sales of these products range from $54 to over $60 billion. Cosmetic products and ingredients are also entering the United States from a growing number

of countries, most of which have regulatory systems and standards that are different from those of the United States. From FY 2004 to FY 2010, the number of cosmetics imports has nearly doubled, growing from less than 1 million import entry lines[1] in FY 2004 to more than 1.9 million import entry lines in FY 2010. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue.

To help address this challenge, FDA and its counterparts in the European Union, Canada, and Japan established a forum in 2007 to exchange ideas and better align practices for maintaining global consumer protection in the cosmetics arena without creating unnecessary obstacles to international trade. The forum, known as the International Cooperation on Cosmetics Regulation (ICCR), meets annually to discuss topics of mutual interest in which cooperation may be possible. The meetings include opportunities for participation by representatives from the cosmetics industry and non-governmental organizations. This year, the United States Government is hosting the annual ICCR meeting July 10-13 in Rockville, Maryland. FDA is working with other ICCR regulatory authorities to hold a stakeholder session with organizations active in the field of cosmetics as well as regulatory officials from additional countries who have expressed an interest in participating in this activity. The session will provide an opportunity for the exchange of viewpoints among a broad range of participants and may identify potential areas for future activities and further alignment. FDA is holding a public meeting on May 15 in advance of the ICCR annual meeting to solicit information, such as agenda topics, from interested parties. Since 2007, ICCR has developed principles for

[1] An import entry line is a portion of an import entry that is listed as a separate item on an entry document. An importer may identify merchandise in an entry in multiple portions; however, an item in the entry having a different tariff description must be listed separately.

addressing cosmetic Good Manufacturing Practices and working documents to address characterization of nanomaterials, and formed a group to address alternatives to animal testing. ICCR continues to work on a variety of other issues related to cosmetics safety and regulation.

In addition to the challenges posed by an increasingly global marketplace, the cosmetics industry is rapidly undergoing significant changes as the technologies used in manufacturing become increasingly sophisticated and the ingredients more complex. The use of nanotechnology may result in cosmetic products or ingredients with different chemical or physical properties than their counterparts that do not contain nanomaterials. Properties and phenomena emerging at the nanoscale may alter the safety, effectiveness, performance, or quality of products—giving rise to both risks and benefits. For example, FDA is conducting research on the ability of different types of nanoscale particles to penetrate skin and on the potential phototoxicity of nano-sized metal oxides used in topical cosmetics. Nanotechnology is an emerging area of science, where there is a critical need to learn more about the potential safety impact.

FDA continues to be actively involved in the National Nanotechnology Initiative, one of the largest federal interagency research and development initiatives, which coordinates funding for nanotechnology research and development among the 26 participating federal departments and agencies. In addition, FDA has a Nanotechnology Task Force to help assess questions regarding FDA's regulatory authorities as they relate to nanotechnology. Through the work

of FDA's task force, last June FDA released a Draft Guidance for Industry entitled "*Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*" to help industry and others identify when they should consider potential implications for regulatory status, safety, effectiveness, or public health impact that may arise with the application of nanotechnology in FDA-regulated products. The Agency is developing draft guidance for industry on FDA's current thinking on the safety assessment of nanotechnology in cosmetics.

The category of products that straddles the line between cosmetics and drugs also presents new regulatory challenges. The industry often refers to these products as "cosmeceuticals," a term which has no legal or regulatory definition in the United States. This class of products presents new regulatory challenges in a number of ways, including how such products should be regulated and with what requirements such products should comply. Many products in this category are advertised as containing "active ingredients," which, by virtue of the ingredients themselves or the claims made for the product, may cause the product to be classified under the FD&C Act as a drug. The use of such ingredients is increasing, and we expect this trend to continue, posing additional regulatory challenges. For example, retinol, an ingredient used in cosmetic anti-wrinkle preparations (as well as OTC drug preparations), was not listed in any cosmetic product ingredient statement in FDA's Voluntary Cosmetic Registration database prior to 2005 but, by the end of 2006, it was listed in 68. It is currently listed in 200 cosmetic product ingredient statements. Peptides, a class of cosmetic ingredient also used in skin-care preparations and associated with certain drug-like product claims, were not listed in any cosmetic product ingredient statements filed with FDA prior to 2005. Currently, there are

over 95 different peptides listed in a total of over 1,200 cosmetic product ingredient statements.

FY 2013 PRESIDENT'S BUDGET

In response to the challenges noted earlier, and to ensure adequate oversight of cosmetics, the FY 2013 President's Budget request includes new legislative authority for FDA to require domestic and foreign cosmetics manufacturers to register with FDA and pay an annual registration fee. The user fees would support FDA's cosmetics safety and other cosmetics-related responsibilities and are estimated to generate $19 million in new resources. The product, ingredient, and facility information submitted with registration would expand FDA's information about the industry and better enable the Agency to develop necessary guidance and safety standards. It would also enable the Agency to identify and address research gaps, for example, about the safety of novel ingredients. With these additional funding resources, FDA would be able to conduct priority activities that meet public health and industry goals.

Specifically, the Agency would conduct the following activities with the new user fee resources:

- Establish and maintain a mandatory Cosmetic Registration Program;
- Acquire, analyze, and apply scientific data and information from a variety of sources, including voluntary adverse event reporting, to set U.S. cosmetics safety standards;
- Maintain a strong U.S. presence in international standard-setting efforts;
- Provide education, outreach, and training to industry and consumers, and

- Refine inspection and sampling of domestic and imported products and apply risk-based approaches to post-market monitoring of domestic and imported products and other enforcement activities.

Overall, the new authority for registration and user fees would strengthen FDA's ability to protect American consumers from potentially unsafe cosmetic products or ingredients.

CONCLUSION

FDA is committed to ensuring the safety of cosmetics used by consumers across the United States. The Agency will continue to work closely with all of its partners on a wide variety of issues important to ensuring cosmetics safety. As Congress considers potential steps to address these issues, we look forward to working with you.

Thank you for the opportunity to discuss FDA's activities to ensure the safety of cosmetics. I would be happy to answer any questions you may have.