



The Honorable Dianne Feinstein
United States Senate
Washington, D.C. 20510-0504

OCT 05 2016

Dear Senator Feinstein:

Thank you for your letter of September 26, 2016, in which you requested information about the Food and Drug Administration's (FDA or the Agency) current regulatory authority over cosmetics and personal care products. We appreciate the opportunity to respond.

During the past several years, Americans have seen a dramatic increase in the numbers and types of cosmetic products on the market. Billions of personal care products, which include primarily cosmetics but also some over-the-counter drugs and some products regulated by the Consumer Product Safety Commission, are sold annually in the United States. 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. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue.

FDA's regulatory authority for cosmetics under the Federal Food, Drug & Cosmetic (FD&C) Act has not been updated (except for color additives) since 1938. Under current law, FDA has much less legal authority to protect consumers from unsafe cosmetics than it does for other products the Agency regulates. Even though Congress has updated FDA's enforcement authorities over other products, it has not done so for cosmetics. As a result, FDA's oversight of cosmetics is limited. The Administration recognizes the need to strengthen FDA's regulatory program for cosmetics, and the President's budget in the past few years has requested authority to require cosmetic firms to register their establishments and products with FDA and to pay a user fee. We appreciate your leadership in sponsoring legislation to provide these authorities as well as others to address limitations in FDA's ability to oversee the safety of cosmetics products.

We have restated your questions below in bold, followed by our responses. We look forward to working with you on these issues.

1. Please describe how a requirement for companies to report adverse health events would change the information you currently have available. How would this impact the Agency's ability to react to potentially harmful products?

Unlike most other FDA-regulated products, currently all reporting of adverse events by companies for cosmetic products is voluntary. We estimate that the adverse event reports we

receive represent only a fraction of the actual number of cosmetic-related problems. The lack of reliable information makes it difficult to assess the true nature of problems with cosmetics and can delay efforts to respond to the complaints. For example, while we had received around 100 adverse event reports about WEN cleansing conditioner hair products, we learned upon inspection that the manufacturer and distributor had received more than 21,000 complaints, including irritation, hair breakage, hair loss, and baldness. The absence of a requirement to submit adverse event reports has significantly delayed our efforts to ascertain and respond to the complaints because we did not learn of them in a timely way.

2. How would a systematic review process of ingredients for safety and the authority to limit or restrict harmful ingredients change FDA's current authority? Please describe the current limitations with the Agency's existing authority to restrict the use of potentially harmful ingredients.

A systematic review process like that described in S.1014 would change FDA's authority in several ways. First, it would allow FDA to restrict harmful ingredients under a more consumer-protective safety standard. Under the FD&C Act, cosmetic products and ingredients, other than color additives, are not required to have FDA approval before they go on the market and manufacturers are not required to submit safety information to FDA. FDA's authority is limited to taking post-market actions against cosmetics that are shown to be adulterated (for example, if it contains a poisonous ingredient that makes the product harmful when used according to directions on the label or in the customary way) or misbranded (for example, if its labeling is false or misleading). Under S.1014, if FDA reviewed a cosmetic ingredient and determined there was insufficient information to show a reasonable certainty of no harm from that ingredient, FDA could restrict the use of that ingredient. The burden would be on the marketers of the ingredient to show that it was safe rather than on FDA to show that it was unsafe.

Second, FDA could use a more streamlined administrative process to reach a regulatory decision on the ingredient. Having a systematic review process that defines the regulatory path for an accelerated implementation of FDA's cosmetic ingredient safety review conclusions would allow the agency to evaluate the safety of cosmetic ingredients as well as restrict or prohibit potentially harmful ingredients in a timely manner to protect public health.

You also asked about current limitations on FDA's ability to restrict the use of potentially harmful ingredients. As described below, FDA's sources of safety information are limited in the following ways:

- **Voluntary Cosmetic Registration Program (VCRP):** Although FDA encourages cosmetic firms to report product formulations through the VCRP, companies are not legally required to tell FDA about their products and safety data, or the location of their manufacturing facilities. As with any voluntary system, we do not have full participation, which limits our knowledge of who is selling cosmetic products in the U.S. and what products are being sold. Mandatory registration and reporting, as requested in the President's budget, would allow us to know what cosmetics are on the market, where they are manufactured, and what ingredients are present in them.

- **Inspections:** FDA can inspect manufacturing facilities to determine if cosmetics are manufactured under sanitary conditions. However, FDA does not have the authority to inspect records on cosmetics, as it does for all other product categories. In addition, because resources are limited, at most 100 firms are inspected each year. Only about 25 are directed (for-cause) inspections. The user fee requested in the President’s budget would be used, in part, to 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.
- **Cosmetic Ingredient Review (CIR) expert panel:** The CIR is an independent, industry-funded panel of medical and scientific experts that meets quarterly to assess the safety of cosmetic ingredients based on data in the published literature as well as information that is voluntarily provided by the cosmetic industry. The industry data may or may not be complete, and the Panel often only reviews summaries of distillations of data rather than raw data from experimental and clinical studies and makes decisions based on this information. FDA takes the results of CIR reviews as well as other sources of information and data into consideration when evaluating safety, but the results of FDA safety assessments may differ from those of CIR.
- **Reports from consumers and health care providers:** Because the law does not require that adverse reactions to cosmetics be reported to FDA, under-reporting is a significant problem and results in a lack of awareness, or an incomplete awareness, of problems. Further, we receive few reports from health care providers, and the reports received from consumers typically lack critical information to help make medical assessments of the problems. Under existing authority, we cannot require cosmetics firms to share their consumer complaints, or their safety data.

3. Does the Agency know where manufacturing facilities are located, what products are imported, and what products are on the market?

Cosmetic manufacturers are not currently required under the law to register with FDA, nor to provide FDA with locations of their manufacturing establishments, the names of their products, or the ingredients in these products. Cosmetic firms may provide this information voluntarily by taking part in FDA’s Voluntary Cosmetic Registration Program (VCRP), but because this information is voluntary, it is incomplete. (See response to question 2).

Based on products examined over the past five years, imported cosmetic products include, for example, products for skin, hair, and eye-area use, as well as for baby care.

4. How does the Agency know the quantity of ingredients in personal care products? Do companies share this information directly?

In general, FDA does not know the quantity of ingredients in personal care products. There is no legal requirement for cosmetic firms to file their cosmetic product formulations with FDA. Additionally, while companies may submit the formulations by participating in FDA’s

Voluntary Cosmetic Registration Program, the information submitted does not include quantities of individual ingredients.

Under the Fair Packaging and Labeling Act, FDA requires cosmetics marketed on a retail basis to consumers to have an ingredient declaration on the label (or, in the case of online and mail order sales, on the company's website, enclosed in the product package, or mailed separately on request). While ingredients are required to be listed primarily in descending order of predominance, this information does not include quantities. Further, "fragrance" and "flavor" may be labeled as such without disclosure of specific ingredients.

When FDA becomes aware of a possible health concern, the agency may purchase cosmetic product samples for analysis. We conduct such analyses based on public health priorities and available resources, and our resources for such analyses are limited.

5. Are there any circumstances where companies must show the Agency their safety studies for the personal care products they sell?

This response addresses only those products that are cosmetics as defined in the FD&C Act, and not all "personal care products" are regulated as cosmetics ("personal care products" is a phrase commonly used to reference a wide range of products, including some non-prescription drugs, medical devices, and dietary supplements, all of which are regulated by FDA; as well as certain consumer products that are regulated by Consumer Product Safety Commission). FDA does not have the authority under FD&C Act to require cosmetic firms to submit to the Agency their safety studies for cosmetic products or ingredients. FDA can request the safety studies as part of an investigation, but the firm decides whether they wish to share the requested information with FDA.

6. What action can FDA take if a product is found to be contaminated and the company refuses to do a voluntary recall? How would mandatory recall authority impact what the Agency can do in this situation?

FDA does not have the authority to require a recall of cosmetics that are in violation of the FD&C Act. FDA can ask manufacturers to voluntarily recall unsafe products. If manufacturers do not remove dangerous products from the market once a safety concern emerges, FDA can issue a press statement to alert consumers, but our only means of legal enforcement action to protect consumers is to bring a court case. FDA, through the Department of Justice (DOJ), can pursue seizure of adulterated or misbranded products and injunctions against firms or individuals who violate the law. DOJ also can take criminal action on FDA's behalf.

In the case of imported cosmetics, FDA may refuse entry of products that appear not to comply with U.S. law. In addition, FDA may place a company or product on an Import Alert. Import Alerts inform FDA field personnel that the Agency has sufficient evidence or other information to detain without physical examination future shipments of an imported article.

Thank you, again, for contacting us concerning this matter. We appreciate and share your interest in the safety of cosmetics marketed in this country. If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Dayle Cristinzio". The signature is fluid and cursive, with a long horizontal stroke extending to the right from the end of the name.

Dayle Cristinzio
Acting Associate Commissioner
for Legislation