SEYFARTH SHAW

One Minute Memo®

A Celebrity Visit to D.C. Calls Attention to Cosmetics Regulations Reform

By Renée Appel and Tonya Esposito

Seyfarth Synopsis: *What brings a celebrity to the Hill? A look at the current state of cosmetics regulations and potential effects of the Personal Care Products Safety Act that has gained famous support.*

An unfamiliar but well-known (and beautified) face graced Capitol Hill with her presence this week at a closed briefing before members of Congress. The celebrity traveled to D.C. to speak about the need for greater regulations of the cosmetics industry and joined the Environmental Working Group (EWG) President Ken Cook and Rep. Frank Pallone Jr. of New Jersey at a Congressional briefing.

A Brief Overview of Cosmetics Regulation Today

Currently, personal care products, which extends to cosmetics, toothpaste, shampoo and other "daily routine" hygiene and beauty items (except soap) are governed by the Food, Drug & Cosmetic Act (FD&C Act) and further governed by the Fair Packaging and Labeling Act (FPLA), which are regulated primarily by the Food and Drug Administration (FDA) and supported by the Federal Trade Commission (FTC).

The FD&C Act establishes that products distributed in the U.S. cannot be adulterated (e.g., contain a poisonous or deleterious substance; consist of filthy, putrid, or decomposed substances; or be prepared, packed, or held under insanitary conditions) or misbranded (e.g., labeling is false or misleading or requisite information is not prominently placed on the label). The FPLA requires that each package of household "consumer commodities" bears a label with a statement identifying the commodity, the name and places of business of the manufacturer, packer, or distributor, and the net quantity amounts of the product's contents. The purpose of the FPLA is to prevent unfair or deceptive packaging and labeling. In addition to the FD&C Act and FPLA, the cosmetics industry is subject to federal and state consumers laws, including the Consumer Product Safety Act (CPSA), Federal Trade Commission Act (FTC Act), and state unfair and deceptive acts or practices.

Despite the requirements under these laws, the safety of cosmetics lies largely in the hands of manufacturers, which has raised concerns from consumers and health advocates. The laws in place do not require specific tests to demonstrate the safety of particular products or ingredients. Manufacturers are also not required to share testing or safety information with the public. Recalls of cosmetics are voluntary actions taken by manufacturers or distributors to remove products from the marketplace that are deceptive or defective. The FDA, however, is not authorized to order recalls of cosmetics, but it may request a product recall if a company does not do so voluntarily.

The FDA and FTC share limited enforcement responsibilities. The FDA can inspect cosmetic manufacturing facilities to ensure cosmetic production safety and to determine compliance under the FD&C Act or FPLA. The FDA's main authority over the cosmetics industry stems from its ability to take regulatory action against companies that produce adulterated or misbranded products. The same authority exists for the FTC regulating labeling and marketing. In addition, the FTC can conduct investigations in which it maintains a coveted subpoena power, can conduct administrative proceedings, and can pursue civil litigation. The FDA has the ability to pursue legal action through the U.S. Department of Justice in the federal court system to remove adulterated and misbranded cosmetics from the marketplace, and on their own or with the assistance of the U.S. Customs and Border Protection, can "seize" products that violate the FD&C Act or FPLA.

The FDA also maintains the Voluntary Cosmetic Registration Program (VCRP), which is a reporting system for manufacturers, packers and distributors. Users of the VCRP who sell products to consumers in the U.S. can register their facilities where cosmetics are manufactured or packed. Users can also file a Cosmetic Product Ingredient Statement for each product distributed in the U.S. But, as reflected in the title, the VCRP is voluntary, not mandatory.

Supplemental efforts to monitor the safety and marketing of the cosmetics industry come from the Cosmetic Ingredient Review (CIR), National Advertising Division (NAD), EWG, and a number of non-governmental organizations. The CIR reviews and assesses the safety of ingredients used in cosmetics and publishes its results in peer-reviewed scientific literature. The NAD examines advertising claims for goods and evaluates consumer complaints, as well as complaints from competing advertisers and local Better Business Bureaus. EWG is a non-profit organization that advocates for a healthier environment through educational campaigns, research, and testing of consumer products.

Cosmetics Reform

About this time last year, Sen. Dianne Feinstein (D-CA) and Sen. Susan Collins (R-ME) introduced the latest version of the Personal Care Products Safety Act (the Bill) to amend the FD&C Act by strengthening the FDA's oversight of cosmetics. The Bill would require products to secure pre-market approval from the FDA before being sold to the public. Currently, cosmetics go straight to market without government testing. In addition to adding the pre-approval hurdle to manufacturers, the Bill would give the FDA tools to further protect consumers. Under the Bill, the FDA would do an annual safety review of five ingredients and contaminants, which would include initially formaldehyde-releasing chemicals and a long-chained paraben. The Bill would further require that personal care product companies register their facilities, permit the FDA to inspect their factories and records, and maintain clean environments for product manufacturing and distribution. To increase transparency and FDA involvement, the Bill would also require that companies disclose their ingredients to the FDA, require specific labeling and warnings for products that contain ingredients not suitable for all populations, require companies to report serious adverse events to the FDA, and allow the FDA to recall dangerous products. To fund these new oversight activities, the Bill would authorize FDA to collect user-fees from personal care products manufacturers similar to what is done for medications and medical devices.

Rep. Pete Sessions reintroduced a similar law at the beginning of last year, titled the Cosmetic Modernization Amendments of 2017, which is viewed as the "small business" alternative to the Senate-proposed Bill.

Final Thoughts

With the current autonomy afforded to the cosmetics industry and the push for greater regulation, manufacturers and distributors should be instilling best practices for reasonable protocols to ensure the safety of their products. A commitment to safe cosmetic products begins at the top (a.k.a. the C-suite) and transpires throughout a company. Evidence of compliance is found in coherent and reasonable written procedures and executed in daily practice by a company, from debating the inclusion of an imported ingredient to scrutinizing over a single word in product packaging. While the Bill suggests that the FDA does not currently pose the biggest threat to manufacturers given the Bill's intent to increase FDA oversight,

manufacturers and distributors alike can face threats to their business from other sources. In particular, potential litigation risk arises from consumers, including damaging class actions. This is especially true provided that educated consumers with expansive research tools via the Internet have taken a more vested interest in reading and understanding personal care products. Adhering to thorough product manufacturing and sound legal advice, not only reduces compliance issues but can also prevent consumer complaints and costly litigation. We'll continue keeping our eye on tracking proposed legislation impacting the beauty and wellness industry.

Tonya Esposito is a partner in Seyfarth Shaw's Washington, D.C. office and is available at tesposito@seyfarth.com.
Renée Appel is an associate in Seyfarth Shaw's Washington, D.C. office and is available at rappel@seyfarth.com.

www.seyfarth.com