LOEB & LOEB LLP

Health and Wellness Marketing Compliance Task Force

ALERT

APRIL 2014

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Lack of Federal Regulation in Cosmetics and Personal Care Products Leads to Litigation Risks

In recent years, consumers have become more focused on the potential for health risks associated with the use of chemicals and other ingredients in cosmetics and personal care products. Many consumers, however, may not realize that the FDA does not require pre-market approval of cosmetics or personal care products such as skin care products, shampoos or sunscreens and does not review or preapprove ingredients manufacturers include in the products themselves. In the absence of federal oversight – and the improbability of such oversight in the near future – states have stepped in to regulate via legislation, and class action litigation continues apace.

In July of last year, the FDA and two cosmetics trade industries (the Personal Care Products Council and the Independent Cosmetics Manufacturers and Distributors) reached a tentative "meeting of the minds" concerning regulatory reforms. The resulting proposed draft legislation by the associations failed to satisfy the FDA, however. In a recent letter, Deputy Commissioner Michael Taylor expressed "profound disappointment" at the proposed legislation. The March 6, 2014, letter criticized the draft bill, saying that the proposed legislation would include preemption provisions of unprecedented scope that would effectively eliminate the states' ability to implement and enforce restrictions and labeling requirements on chemicals used in cosmetics and personal care products while purporting to vest the FDA regulatory oversight of the industry that, in reality, would hamper or prevent the FDA from ensuring the safety of cosmetics and personal care products. The letter concludes by calling off further negotiation with the industry associations.

Other proposed federal legislation, such as the Safe Cosmetics and Personal Care Products Act of 2013 and its predecessors (*e.g.*, the Safe Cosmetics and Personal Care Products Acts of 2010), have stalled in the legislative process hamstrung by a divided Congress and appear unlikely to pass any time soon.

Even before the current standstill in efforts to negotiate uniform legislation at the federal level, states had stepped into the regulatory void. California's Proposition 65 is perhaps most notable, not only for the fact that it was enacted in 1986, nearly two decades ago, but also that the list of substances known to cause cancer or birth defects has grown to more than 800 chemicals. Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, requires, among other things, that businesses warn consumers of "significant" amounts of chemicals in household products for purchase unless exposure is low enough to pose no significant risk of cancer or is significantly below levels observed to cause birth defects. The state has established safe harbor levels for more than 300 chemicals, and exposure at or below these levels does not require a warning. In the past several years, California has added several chemicals frequently found in personal care products to the Proposition 65 list, including titanium dioxide and cocamide-DEA, a chemically

modified form of coconut oil used in shampoo and other products as a foaming agent.

The California Department of Toxic Substances Control also recently released the first list of priority products, three consumer products that contain one or more of the chemicals on the Proposition 65 list that the department is asking manufacturers to investigate whether safer ingredient alternatives exist for the products or to stop selling the products within the state. While none of the priority products are cosmetics or personal care items, the department intends to publish a longer list in October, along with its three-year working plan. The list of priority products is part of California's Green Chemistry Initiative to encourage manufacturers to review whether they can manufacture their products using safer and more natural alternatives to ingredients already identified by the agency as potentially harmful. Manufacturers that want to sell these priority products in California will be required to conduct an alternatives analysis to assess whether feasible safer ingredients are available. The department won't require alternatives testing until it issues its final list of priority products, which is currently expected in April 2015.

A number of other states have adopted legislation intended to identify hazardous chemicals in consumer products, and some states, including New York and Massachusetts, have advancing legislation that would specifically require cosmetic makers to report all products containing cancer-causing or toxic chemicals. The scope of the bills varies across the country, with some legislation taking a general Proposition 65 "list" approach and others targeting specific substances, such as formaldehyde. Even as the regulatory landscape is becoming more crowded and more fragmented – creating increasing complexity for manufacturers of personal care products – science continues to evolve, making compliance somewhat of a moving target.

The lack of comprehensive federal regulation combined with the patchwork of laws at the state level create challenges for manufacturers and distributors of cosmetics and personal care products. Exploiting uncertainty in the law, the number of consumer class actions alleging the use of toxic or unsafe ingredients continues to rise. And while the addition of more chemicals and ingredients to state lists is causing personal care products and cosmetics to be targeted in consumer litigation, plaintiffs are also filing class action lawsuits challenging the safety of ingredients that do not appear on the Proposition 65 (or any) list as plaintiffs' counsel become increasingly sophisticated about the science behind ingredients and whether such substances are sufficiently "safe."

For more information on the content of this alert, please contact Michael Mallow at mmallow@loeb.com or 310.282.2287 or Liv Kiser at lkiser@loeb.com or 312.464.3170.

Loeb & Loeb LLP's Health and Wellness Marketing Compliance Task Force

Our Task Force was formed in response to the increase in regulatory enforcement actions and consumer class action lawsuits targeting producers and sellers of food, health and beauty products. The FTC and States Attorneys General are closely scrutinizing marketing and advertising practices looking for misleading product claims, including product misbranding and mislabeling. The regulatory framework governing the labeling and marketing of food, health and beauty products is ambiguous at both state and federal levels and, as a result, there has been a proliferation of lawsuits over marketing and advertising practices in this space. Our Task Force helps companies avoid liability, manage risk and defend against consumer class actions and regulatory enforcement.

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