The Campaign for Safe Cosmetics

FDA Regulatory Shortcomings over Cosmetics

The FDA's Office of Cosmetics and Colors has regulatory jurisdiction over cosmetics and personal care products. Most people assume the FDA regulates these products in the same way it does food and drugs to assure safety. In fact, cosmetics are one of the least regulated consumer products on the market today.

FDA's Lack of Authority

The Federal Food, Drug and Cosmetics Act (FFDCA) includes 112 pages of standards for food and drugs, but just a single page for cosmetics. The cosmetics title of the FFDCA, which has not been amended significantly since it was enacted more than 70 years ago, provides virtually no power to perform even the most rudimentary functions to ensure the safety of an estimated $50 billion cosmetic industry.

What FDA Cannot Do

- Require companies to conduct pre-market safety testing of cosmetics products and ingredients.
- Review or approve cosmetic products or ingredients before they are sold to the public.
- Effectively and efficiently regulate cosmetics products without facing cumbersome legal proceedings with manufacturers.
- Require product recall. The agency must go to court to remove misbranded and adulterated products from the market.
- Require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries. Instead, FDA relies on voluntary reporting of ingredients, injuries and establishments.

What the FDA Does Not Know

- The overall number of ingredients in personal care products.
- The ingredients in a particular product that lists "fragrance" as a mask for dozens of component chemicals.
- The number and location of companies that manufacture and distribute personal care products. The FDA's primary enforcement tool is facility inspections, but they can't inspect facilities they don't know exist.
- The extent of health impacts from harmful ingredients. Companies are not required to report adverse health effects to the FDA or share studies they may have conducted on chronic health effects.
- The presence or potential health impact of nanomaterials in cosmetics.

Voluntary and Industry Self-Regulation Are Not Working

Cosmetic Ingredient Review (CIR). In the absence of government authority, the safety of personal care product ingredients is evaluated through a voluntary industry program known as the Cosmetic Ingredient Review process. Not only is this program run by the very industry it is intended to oversee, but compliance with CIR recommendations is totally voluntary. The CIR has reviewed less than 20% of the FDA estimated 12,500 chemicals used in cosmetics, and of those the CIR has reviewed, they have found only 9 chemicals unsafe for use in cosmetics.

What safety data does exist focuses on acute reactions to products, such as skin rashes or allergic reactions, as opposed to studies that look at chronic health effects from chemicals in personal care products, like cancer, reproductive or nervous system effect that are driven by genetic susceptibility, the timing of exposure, and aggregate exposures over a lifetime.

FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP collects information on product ingredient listings and registration of manufacturers, packers and distributors. Again, participation in the program is entirely voluntary.

- FDA *estimates* 12,500 cosmetic ingredients, and a similar number of fragrance ingredients, but has formal records for only 4,066. Environmental Working has documented 8,821 unique ingredients in their online product database (www.cosmeticdatabase.com).
- FDA e*stimates* that cosmetics are manufactured in more than 1,400 domestic establishments. However a GAO study stated: "Because FDA cannot mandate participation, it cannot accurately assess how many companies may be avoiding registration."

PCPC's Consumer Commitment Code. The Personal Care Product Council's Consumer Commitment Code encourages voluntary reporting of adverse health events. Companies are asked to report "serious and unexpected adverse consumer experiences with cosmetic products." However, not only is the program voluntary, but FDA must pro-actively file a written request for the information "based on an explicit, legitimate and specific safety concern or question related to the product" and inspect the safety information summary at "a mutually agreed upon location." This process requires the FDA to spend scarce resources filing formal requests for information that should be submitted to them automatically given the threat to public health presented by adverse health events associated with cosmetic use.

Please support the *Safe Cosmetics Act of 2010* which gives the FDA's Office of Cosmetics and Colors the authority and resources it needs to provide more effective oversight of the cosmetics industry.

For more information, please contact Jason Rano, Environmental Working Group, jrano@ewg.org or Janet Nudelman, Breast Cancer Fund, jnudelman@breastcancerfund.org.

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