



December 19, 2008

To: Dr. Josh Sharfstein
From: Janet Nudelman, Director of Program and Policy, Breast Cancer Fund
Re: FDA strengthened oversight and regulation of the cosmetics industry

Problem Statement

Most people assume the Food and Drug Administration (FDA) regulates cosmetics the same way it does food and drugs to ensure they are safe. In reality, the cosmetics are among the least regulated products sold to consumers.

Due to gaping holes in federal law, it's perfectly legal for cosmetics companies to use unlimited amounts of virtually any ingredient including chemicals linked to cancer, reproductive and developmental harm, and other adverse health impacts, with no premarket safety assessment. As a result, cosmetics sold in the US contain ingredients and impurities with known health hazards, including lead, mercury, hydroquinone, coal tar, formaldehyde, 1,4 dioxane, acrylamide, phthalates and even placenta.

An Environmental Working Group (EWG) analysis of cosmetic ingredients cross referenced against 50 definitive government, industry, and academic databases of hazardous chemicals revealed that more than 1 in 5 of all the personal care products on store shelves today contain chemicals linked to cancer, 80% contain ingredients that commonly contain hazardous impurities, and 56% contain penetration enhancers that help deliver ingredients deeper into the skin (EWG 2008).

The federal law that governs the \$50 B cosmetics industry – which is the same size as the biotech industry - is 2.5 pages long and hasn't been amended since it was introduced 70 years ago.

In the absence of government authority, the safety of personal care product ingredients is evaluated through an industry funded and self-policing body, the Cosmetic Industry Review (CIR) Panel. In the 30 years since its creation, it has only evaluated only 11% of the 12,500 ingredients used in cosmetics—meaning that the vast majority have not been assessed for safety by the FDA, CIR or any other publicly accountable body.

To the detriment of public health, the CIR doesn't look at the effects of exposures to multiple chemicals linked to negative health impacts; the cumulative effect of exposures over a lifetime; the timing of exposure which can magnify the harm for the very young and other populations; or worker exposures, in both beauty salons and manufacturing plants.

This panel operates with virtually no guidance from FDA when it comes to the safety of personal care products. Words on labels like "natural," "safe" and "pure" have no definition in law and no



relationship to the hazards of the ingredients used in cosmetics. Acceptable levels of risk are entirely at the CIR's discretion.

The emerging evidence on the body burdens of chemicals in the American people as well as the new science on how small exposures to these chemicals can add up to harm argues the need for stricter FDA oversight and regulation of the cosmetics industry.

Solution: Support legislation that would give the FDA the authority it needs to ensure that cosmetics do not contain ingredients linked to adverse health effects.

Core principles and policies that are needed to protect the safety and health of the American people from unsafe chemicals in the cosmetics and personal care products they use every day include:

- Pre-market safety assessment of all cosmetic ingredients.
- A ban on ingredients and toxic impurities in ingredients or products linked to cancer, birth defects, infertility, neurotoxicity, endocrine disruption or other adverse health endpoints.
- Full ingredient listing on product labels and company Web sites, including the constituent ingredients of fragrance, nanomaterials and salon products.
- FDA guidance on substantiating the safety of ingredients used to formulate cosmetics.
- Data sharing to avoid duplicative testing and encourage alternatives to animal testing.
- A grants program to encourage the creation of innovative solutions and safe alternatives to toxic chemicals in cosmetics.
- Mechanisms that create a level playing field so small businesses are not unfairly burdened by federal regulations that require safer products.
- Adequate funding so FDA Office of Cosmetics and Colors has the support it needs to provide effective oversight of the cosmetics industry.

References:

EWG (Environmental Working Group). 2008. Skin Deep Cosmetic Safety Database. <http://www.cosmeticdatabase.com>. FDA (U.S. Food and Drug Administration). 2007.



Compliance Program Guidance Manual. Program 7329.001. Chapter 29 – Colors and Cosmetics Technology. Available for download at <http://www.cfsan.fda.gov/~comm/cp-toc.html>. Accessed May 11 2008.

Additional background and resources:

Campaign for Safe Cosmetics: www.safecosmetics.org