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May 12, 2015

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Toxic Chemicals in Cosmetic Products

Dear Dr. Ostroff:

The nail salon industry in New York City is in need of immediate reform. It seems clear that both workers and clients are being exposed to several potentially harmful chemicals that are routinely used in salons. Workers, advocates, and an increasing number of scientists are claiming that when used in nail salons, these chemicals may be associated with difficulties in pregnancy, cancers, bronchial irritation, painful skin conditions, and developmental issues in children. It is particularly disturbing that the workers who face the brunt of these health hazards are largely immigrant women, who work for low wages and are often subjected to wage theft and other illegal employer practices.

The New York City Department of Consumer Affairs is writing to urge the Food and Drug Administration (“FDA”) to take immediate action to protect nail salon workers and consumers by issuing rules that would ban the use in cosmetic products of the so-called “toxic trio” of chemicals: toluene, formaldehyde and dibutyl phthalate (DBP).

The nail salon industry is booming. According to census data, there are more than 17,000 nail salons in the United States. The U.S. Bureau of Labor Statistics reports that salons employed approximately 87,000 workers in 2012 and that number is expected to grow by 16% in 2022. New York City is the nail salon capital of the United States, with salons dotting the streets of every neighborhood. An estimated 2,000 nail salons in New York City employ a reported 13,100 nail salon workers.

Nail salon workers are exposed to products containing toxic chemicals that can cause chronic and reproductive harm. Under the Federal Food, Drug, and Cosmetic Act, cosmetic products sold in the United States cannot be “adulterated”—they must be free of poisonous or harmful substances that might injure users when used as labeled or under the usual conditions of use. Despite this prohibition, many widely used cosmetic products contain the toxic trio.

These hazardous chemicals have been linked to reproductive harm, respiratory problems and cancer. Toluene, a solvent that helps nail polish go on smoothly can impact the central nervous system and can also cause irritation of the eyes, throat and lungs and is a possible reproductive toxin; formaldehyde, a nail hardening agent is a known carcinogen; and DBP, a chemical that keeps nail polish flexible is known to interfere with reproductive hormones.

It is clear that the FDA and the public cannot rely on the cosmetics industry to police itself. In the face of mounting evidence that the toxic trio causes significant health problems to salon workers, the industry continues to maintain that they are safe. And, according to a 2012 California study, some products claiming to be non-toxic and even “three free” still contained the toxic chemicals. The FDA recently criticized the Personal Care Products Council and Independent Cosmetics Manufacturers and Distributors—the major industry trade organizations—for proposing legislation that would reduce the FDA’s ability to take action against dangerous cosmetics and effectively eliminate any state authority to regulate these products.

We recognize that the FDA’s authority over cosmetics such as nail products is far less comprehensive than its authority over other FDA-regulated products with regard to registration; testing; premarket notification, clearance, or approval; good manufacturing practices; mandatory risk labeling; adverse event reports; and recalls. We support efforts to expand the FDA’s authority to effectively regulate the cosmetics industry.

The FDA cannot, however, wait for legislative reform to act to protect salon workers and consumers from the potential health risks posed by the toxic trio. The FDA can rely on guidance from OSHA regarding the dangerous health effects of the toxic trio; studies conducted by the State of California demonstrating the danger of these products to salon workers; and the extensive information the FDA already possesses—as found on its website—regarding the dangers posed by allowing these chemicals in cosmetic products. The conditions of many salons – multiple workstations where these products are used simultaneously with limited ventilation and without personal protective equipment -- increases the likelihood that these chemicals, typically evaluated for their safety as personal use items, concentrate in air, making their use more industrial than individual.

Using this extensive information, the FDA can issue rules determining that toluene, formaldehyde and DBP are poisonous or deleterious substances that may cause injury to users under customary use and that those products that contain those substances are “adulterated.” In 2004, the European Union (EU) banned the use of DBP in cosmetic products and has since set regulations to limit the use of toluene and formaldehyde. Rules banning the use of these ingredients will allow the FDA to engage in enforcement, including seeking injunctions against companies distributing the products, seizing products and seeking criminal penalties against their manufacturers. Their effort demonstrates that safer alternatives are available and the products are available in reformulations. The FDA has issued similar rules with regard to ingredients in cosmetics products including bithionol, which had been used as an antibacterial agent in cosmetic preparations such as detergent

bars, shampoos, creams, lotions, and bases used to hide blemishes; vinyl chloride, an ingredient that had been used in cosmetic aerosol products including hair sprays; and chloroform which had been an ingredient in cosmetic products. We urge the FDA to act quickly to protect salon workers and consumers from the health effects of the toxic trio.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julie Menin', written in a cursive style.

Julie Menin
Commissioner