AMERICAN NURSES ASSOCIATION

8515 Georgia Avenue, Suite 400
Silver Spring, Maryland 20910-3492
301 628-5000 • Fax 301 628-5001
www.NursingWorld.org

Rebecca M. Patton, MSN, RN, CNOR
President

Linda J. Stierle, MSN, RN, CNAA,BC
Chief Executive Officer

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

The American Nurses Association (ANA) welcomes this opportunity to comment on the Federal Register/Vol.73, No. 181 on September 17, 2008 notice for DHHS Docket # FDA-2008-N-0490,Voluntary Cosmetic Registration Program.

The ANA urges the United States Food and Drug Administation to continue its Cosmetic Registration Program, but change it from voluntary to mandatory. Americans may believe that the US government has tested and assured the safety of cosmetics before their release into the market place. In actuality, major loopholes in federal law prevent the US FDA from approving the safety of cosmetics before they can be sold. There are no full disclosure requirements for pre-market testing, nor is there a system for reporting unexpected side effects for cosmetics and personal care products. There are no formal recall mechanisms currently in place. The FDA has no authority under the Food, Drug and Cosmetic Act to order a recall of a cosmetic. The ANA appreciates that all color additives used in cosmetics must be FDA approved, meet identity and specification requirements stated in the Code of Federal Regulations (CFR) and in some other cases meet other requirements, but this is not enough. This docket clearly states "filing of cosmetic product formulations is not mandatory" yet these *voluntary* "filings provide FDA with the best information available about cosmetic product ingredients and their frequency of use…… and assists FDA scientists in evaluating reports of alleged injuries and adverse reactions from the use of cosmetics….also is used in defining and planning analytical and toxicological studies pertaining to cosmetics". The FDA obviously requires ***all*** cosmetic formulations to do their job thoroughly and adequately, not just those cosmetic formulations that industry chooses to share. This should also include confidential information, so called "trade secrets", fragrances, flavorings and inert ingredients. These ingredients' disclosures are crucial to alert consumers and regulatory agencies of toxic ingredients and potential allergens.

In 2006, the ANA's House of Delegates passed a resolution on "Nursing Practice, Chemical Exposure and Right-to-Know". This resolution advocates for: reducing the use of toxic chemicals; requiring that less harmful chemicals be substituted whenever possible; supporting labeling and full disclosure mechanisms; demanding adequate information on the health effects of chemicals and chemicals in products before they are introduced on the market; creating more streamlined methods for chemicals to be removed from use and supporting research efforts in environmental health to better understand the relationship between health and the environment. ANA endorsed and has signed on to the "National Campaign for Safe Cosmetics".

ANA has encouraged ANA Constituent Member State Nurses Associations to do the same in order to educate nurses and the public to take precautions when using cosmetics and personal

care products, also urging US cosmetic companies to sign a compact to remove untested chemicals from cosmetics by 2010.

Finally, the ANA adopted the precautionary approach in October, 2003. The precautionary principle states "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" according to the Wingspread conference held in 1998. This principle is an excellent guide. It shows the opportunity for prevention, instead of having to backtrack and rectify matters after they have already caused harm.

ANA asks the FDA to:

1. Change the Voluntary Cosmetic Registration Program from voluntary to mandatory.
2. Require stricter labeling requirements:
   a.) Use of signal terms such as "caution", "warning", and/or "danger" with clear, understandable language detailing any potential adverse health impacts of product ingredients.
   b.) Elimination of the designated "confidential business information". Require all ingredients, "trade secrets" or not, to be listed on labels. "Fragrance" and/or "flavoring" are not to be exempted from this full disclosure.
3. Ensure that all cosmetics are free of chemicals that are known or strongly suspected of causing cancer, mutation or birth defects and replaced with safer alternatives.
4. Require pre-market safety testing for carcinogenicity, mutagenicity, reproductive hazards while continuing testing for skin irritation, allergenicity and sensitivities.
5. Eliminate self-regulating industry oversight. The US FDA should instead provide industry oversight by: enforcing new and existing regulations, performing manufacturer inspections, ensuring unbiased product safety testing and assuring safety assessments that address multiple chemical exposures from a variety of products.
6. Support industry research that results in the development of safe cosmetics.

Again, thank you very much for the opportunity to comment on this important issue.

Sincerely,

Nancy L. Hughes, MS, RN
Director, Center for Occupational and Environmental Health
American Nurses Association