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

Submitted electronically to <http://www.regulations.gov>

Re: Department of Health and Human Services, Food and Drug Administration, Docket No. FDA-2011-N-0770; Cosmetic Microbiological Safety Issues; Public Meeting

To Whom It May Concern:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on Cosmetic Microbiological Safety Issues. The ANA will limit said comments to the FDA's request to present information on "any other issues relevant to the microbiological safety of cosmetics" on page 67461.

The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of healthcare professionals in the United States. ANA represents registered nurses in all roles and practice settings, through constituent member nurses associations and organizational affiliates. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and advocating before Congress and regulatory agencies on health care issues affecting nurses and the public.

ANA commends the FDA's commitment to ensuring that cosmetics are properly labeled, safe for consumers, and free of adulterations as noted on page 67461. ANA supports the FDA in this endeavor.

Nurses have a stake in cosmetic safety issues since nurses not only apply cosmetics, including skin moisturizers and shampoos, to themselves and family members, but to patients. Nurses need assurance that when they encourage a new mother to bathe her baby or assist a chemotherapy patient with makeup application that no harm will come to these individuals by the cosmetic application. An assurance of no harm includes that not only is the product preserved adequately to prevent microbiological growth, but also that the preservative used in the product is not harmful, as well.

ANA is actively involved in forming public policy that affects human health and patient advocacy. As a member of the Campaign for Safe Cosmetics, ANA recognizes that cosmetics and personal care products need to be free from *all* harmful contaminants to secure patient, nurse and public health.

Formaldehyde and formaldehyde-releasing preservatives, such as quaternium-15 are often found in cosmetics. They can be skin sensitizers (<http://safecosmetics.org/article.php?id=599>) and the National Toxicology Program determined formaldehyde to be “known to be a human carcinogen” in their *Report on Carcinogens, Twelfth Edition*. Furthermore, NTP stated that environmental exposure to formaldehyde comes primarily from indoor/outdoor air, tobacco smoke, and the use of cosmetics containing formaldehyde. The *Report* continued by explaining that the use of formaldehyde releasers in cosmetics is widespread—research showed approximately twenty percent of cosmetics contained formaldehyde or formaldehyde-releasing preservatives (<http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/Formaldehyde.pdf>).

As such, ANA requests that the FDA:

- Require cosmetic product labels to include a list of *all* ingredients found in the end product, including preservatives and fragrance.
- Examine formaldehyde-free preservatives currently used in cosmetics for their efficacy and safety.
- Establish a list of safe alternatives for formaldehyde and formaldehyde-releasing preservatives.
- Set a timeline for the removal of formaldehyde and formaldehyde-releasing preservatives from cosmetic and personal care products, particularly those for use in vulnerable populations, such as infants, children, the immuno-compromised and women of child-bearing age.
- Include a list of safe alternatives for formaldehyde and formaldehyde-releasing preservatives in any FDA guidance document on “Cosmetic Microbiological Safety Issues.”

### **Conclusion**

ANA applauds the FDA on taking this important step towards ensuring safer cosmetics. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Holly Carpenter, BSN, RN, Senior Staff Specialist, Center for Occupational and Environmental Health at [holly.carpenter@ana.org](mailto:holly.carpenter@ana.org) or 301-628-5105.

Thank you for the opportunity to comment on this important issue.

Sincerely,

  
Marla J. Weston, PhD, RN  
Chief Executive Officer  
American Nurses Association

cc: Karen A. Daley, PhD, MPH, RN, FAAN  
President  
American Nurses Association