SDA The Soap and Detergent Association

February 10, 2004

Linda Katz, M.D.
Director, Office of Cosmetics and Colors HFS-100
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dr. Lester M. Crawford
Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Drs. Crawford and Katz:

The Soap and Detergent Association understands that the Food and Drug Administration (FDA) is in the process of writing an interim final rule banning certain materials from FDA-regulated human food and cosmetics as outlined in a January 26, 2004 press release. The press release noted that the rule, effective immediately upon publication, would ban any material from downer or dead cattle as well as specified risk materials (SRMs) from use in food, dietary supplements and cosmetics.

SDA represents the North American producers of oleochemicals, including those derived from animal sources. SDA and its members share your commitment to assure the safety of the tallow supply used in cosmetics as well as other affected products. While sharing your safety commitment, SDA is nevertheless concerned about the potentially significant impact which an immediate effective date would have on our members' ability to source tallow under the conditions of the interim rule as described to date.

We urge the FDA to include a realistic implementation period, a period of enforcement discretion or some similar mechanism in the proposed interim final rule. In view of the nature of our production processes, we believe such provisions can be instituted without compromising the public health.

We are in the process of quantifying the impact which the proposal, as we know it, would have on companies and their manufacturing operations. We will share this analysis with you shortly; however, given the urgency with which the FDA is working on this interim

2004N-0081 C2

final rule, we wanted to provide a brief overview of the concerns raised by our member companies.

SDA and its member companies are supportive of FDA's recent statements acknowledging the safety of cosmetics and assuring the public that there is no risk of BSE from these products. In 1997, the SDA conducted a survey of the oleochemical industry's processes which was presented to the Center for Drug Evaluation and Research BSE Working Group of the FDA on August 11. All indications at that time were that the processes employed were successful in deactivating any prions. SDA members take their stewardship responsibilities very seriously. The 1997 document and subsequent interactions with the FDA are part of that heritage. SDA member companies are committed to ensuring the safety of their products against the risks posed by BSE. SDA looks forward to working with the agency to enhance existing firewalls to protect American consumers. These firewalls should be based upon sound science.

As FDA works to implement these additional firewalls, it is important for the agency to understand current industry practices so as to mitigate to the extent possible substantial disruptions in the marketplace. While the details of the final regulation are unknown, including what will be covered, the fact that the interim final rule will be effective upon publication holds the potential to create extreme disruptions for companies.

For example, companies that are currently using inedible tallow, which contains specified risk materials, will find it difficult to comply immediately. These companies will need to secure commitments from suppliers for edible or edible/technical tallow, which does not include downers or SRMs. This will create a significant new demand for edible tallow. Questions have been raised about whether the supply of edible/technical tallow is adequate to meet these new demands. Further, as formulators switch to edible tallow, formulas may need to change, as edible and inedible tallow have different characteristics and odor. This will also require time.

SDA members are profoundly concerned about whether the edible tallow supply is sufficient to meet these new demands. Since the amount of tallow in the market is dependent upon the number of cattle slaughtered, rather than the demand for tallow, new supplies will not be immediately forthcoming. Over time inedible tallow suppliers may change their operations to provide tallow without SRMs and downer/dead cattle, but this will take time and capital expenditures. In the meantime, inedible and edible tallow users will be competing for a finite resource. Shortages in the marketplace for edible/technical tallow will likely occur.

As noted above, SDA is seeking additional detailed information from its member companies about the potential dislocation in the tallow marketplace. We will share this information with you as soon as it is consolidated. In the meantime, we hope that you will consider a delayed effective date, a period of enforcement discretion or some similar mechanism to allow time for changes in the production of tallow and tallow derivatives. This period would allow changes in slaughtering and specified risk material disposal

February 10, 2004

processes to occur as well as allow an orderly transition for the required material to fill the distribution channels of the oleochemical markets.

The SDA looks forward to working with you on this matter. Your primary contact at SDA is Dennis Griesing, our Vice President, Government Affairs. He can be reached at 202-662-2518 or via e-mail at dgriesing@sdahq.org.

Sincerely,

Ernie Rosenberg
President

cc: Daniel Troy, Chief Counsel