



October 12, 2004

E. Edward Kavanaugh  
President

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

Re: Use of Materials Derived From Cattle in Human Food and  
Cosmetics; Interim Final Rule; Docket No. 2004N-0081  
69 Fed. Reg. 42256 (July 14, 2004)

Dear Sir or Madam:

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits these comments in response to the interim final rule published by the Food and Drug Administration (FDA) to prohibit the use of certain cattle material in cosmetics. The interim final rule is intended to minimize human exposure to materials that may be contaminated with the agent that causes bovine spongiform encephalopathy (BSE).

CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States, and companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories. Members of CTFA have a great interest to ensure that their products continue to be safe for consumers.

Section 700.27(b) of the Interim Final Rule that is the subject of these comments provides that no cosmetic shall be manufactured from, processed with, or otherwise contain, "prohibited cattle materials." The term "prohibited cattle materials" is defined in Section 700.27(a)(1) to include five types of cattle materials, namely, "specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or MS(Beef)." The term "prohibited cattle materials" specifically excludes "tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives."

Section 700.27(a)(6) provides that if "tallow" is to be used in cosmetics, it "must be free of prohibited cattle risk material or must contain not more than 0.15 percent hexane-insoluble impurities." The term "tallow derivative" is defined in

2004N-0081

C129

Section 700.27(a)(7) to mean “any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow.”

In the preamble to the regulation, FDA stated: “Because we believe that tallow has negligible risk of transmitting BSE, and tallow derivatives undergo additional processing, we do not believe that tallow derivatives pose a risk of transmitting the agent that causes BSE to humans.” 69 Fed. Reg. 42246, at 42261. Given that tallow derivatives can be produced from either tallow or another product (e.g., vegetable oil) as the starting material, there has been some confusion as to whether these chemicals are subject to the final rule and the related recordkeeping requirements of proposed Section 700.27(c)(1). We request that the agency further clarify in the final rule that all tallow derivatives are exempt from the interim final rule.

Milk is prohibited from use in cosmetics as “prohibited cattle materials” because the cattle from which it comes are “not inspected and passed.” We believe this is an unintended result and urge FDA to clarify that milk and its byproducts are excluded from Section 700.27(a)(1).

CTFA and its members agree that tallow and other cattle materials that contain no prohibited cattle materials, tallow that contains no more than 0.15 percent hexane-insoluble impurities, and tallow derivatives are completely safe for use in cosmetics.

As the national trade association representing the personal care product industry, CTFA and its members support FDA’s efforts to ensure the continued availability of cosmetic products that are free from potential BSE contamination. We would appreciate action by the Agency to clarify the issues raised above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas J. Donegan', written in a cursive style.

Thomas J. Donegan  
Vice President – Legal and General Counsel