



Pamela G. Bailey
President & CEO

November 7, 2005

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

Re: Use of Materials Derived from Cattle in Human Food and
Cosmetics; Interim Final Rule; Docket No. 2004N-0081, 70 Fed.
Reg. 53063 (Sept. 7, 2005)

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) on September 7, 2005, that amends its previous interim final rule on the use of materials derived from cattle in human food and cosmetics (69 FR 42256, July 14, 2004).

CTFA is a 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.

On October 12, 2004, CTFA submitted comments requesting FDA to clarify certain aspects of the July 14, 2004, interim final rule. CTFA acknowledges FDA's response to these concerns in the amendments provided for in the September 7, 2005, interim final rule. Specifically, the agency clarified that all tallow derivatives, regardless of their source, and milk and milk products are excluded from the definition of "prohibited cattle materials." CTFA also supports the other amendments provided for in the September 7, 2005, interim final rule.

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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. CTFA and its members support FDA's efforts to ensure the continued availability of cosmetic products that are free from potential BSE contamination.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas J. Donegan', with a long horizontal flourish extending to the right.

Thomas J. Donegan
Vice President – Legal and General Counsel

cc: Robert E. Brackett, Ph.D.
Linda M. Katz, M.D.