

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0291]

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**Risk Assessment for Cosmetics and Potential Contamination With Bovine Spongiform Encephalopathy Agent; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a risk assessment regarding the potential for variant Creutzfeldt-Jakob Disease (vCJD) in humans from exposure to cosmetics containing cattle-derived protein infected with the bovine spongiform encephalopathy (BSE) agent. FDA is making this document available to communicate publicly the potential risk to public health from cosmetics made with cattle materials that may be contaminated with the BSE agent.

**ADDRESSES:** Submit written requests for single copies of the risk assessment to the Office of Plant and Dairy Foods (HFS-365), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the document may be sent. Alternatively, you may request a copy of the document by calling 301-436-2367, or you may fax your request to 301-436-2632. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the risk assessment.

**FOR FURTHER INFORMATION CONTACT:** Morris Potter, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 404-253-1225.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Cosmetics may be made from a variety of cattle-derived ingredients. These ingredients include: Albumin, brain extract, brain lipid, cholesterol, fibronectin, sphingolipids, collagen, keratin, and tallow, and tallow derivatives. Tallow derivatives, particularly fatty acids and glycerin, are the predominant cattle ingredient used by the cosmetic industry. Cattle-derived ingredients serve many functions and may be used as skin conditioning agents, emollients, binders, and hair and nail conditioning agents.

There are several routes through which cosmetics contaminated with the agent that causes BSE could transmit disease to humans. Transmission of the BSE agent to humans through intact skin is not likely; however, cosmetics may be ingested or applied to cut or abraded skin or to mucosal tissues, particularly in the eye, which could provide direct routes for infection.

**II. Risk Assessment for Cosmetics and Potential Contamination With the BSE Agent**

The risk assessment presents scientific evidence on the risk of transmission of vCJD to humans from cattle-derived ingredients used in the manufacture of cosmetics. FDA has prepared a qualitative assessment that follows the generally accepted framework for risk assessments endorsed by the Codex Alimentarius Commission. This framework involves the following steps:

(1) *Hazard identification.* A review of available information on vCJD and its link to BSE-infected cattle.

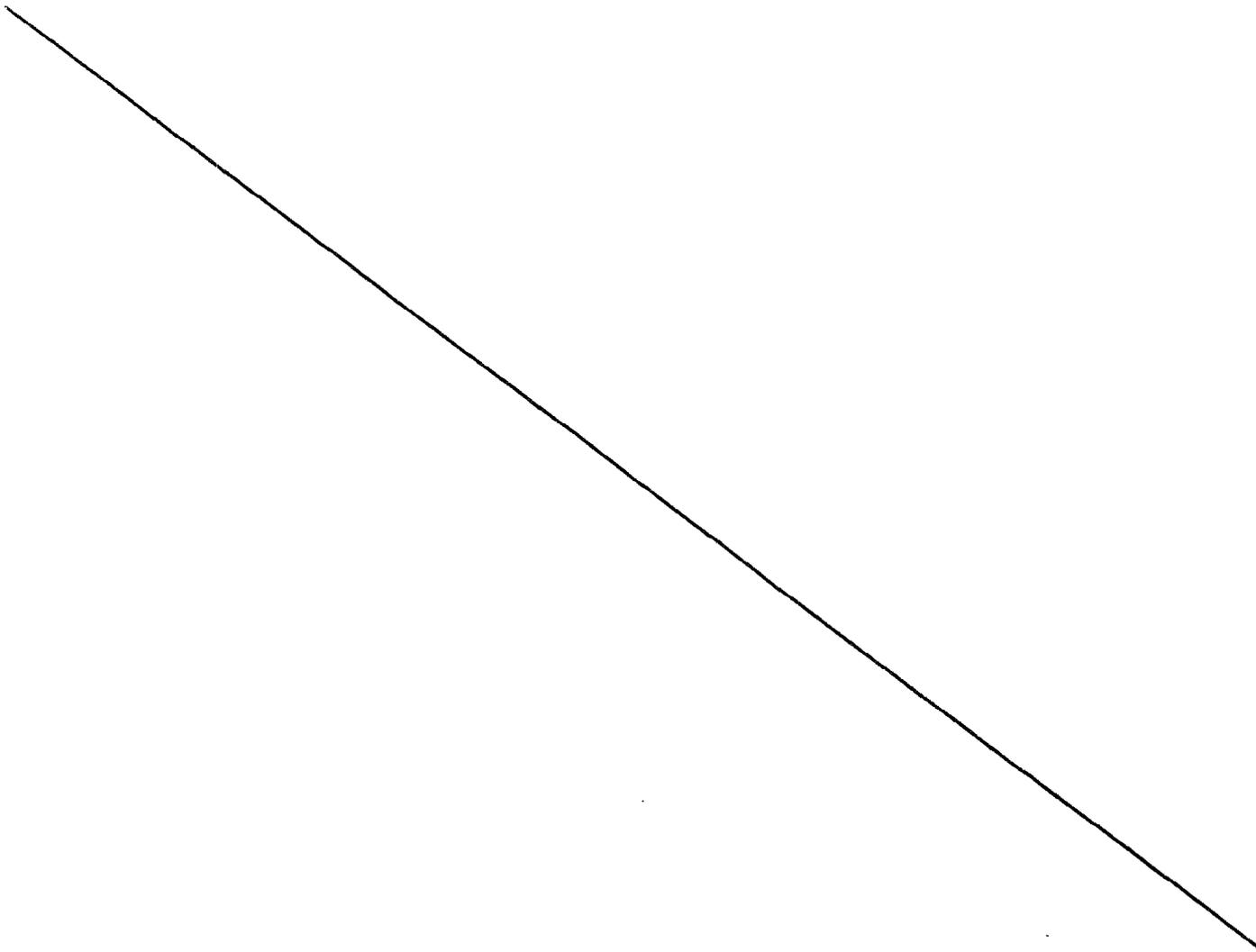
(2) *Exposure assessment.* An evaluation of the range of possible cattle-derived ingredients that might be used in the manufacture of cosmetics and the likelihood that a contaminated cosmetic results in transmission of the BSE agent to humans.

(3) *Hazard characterization.* The assessment of the potential for BSE transmission and development of vCJD in humans.

(4) *Risk characterization.* The integration of information on potential hazards with the exposure assessment.

The risk assessment also discusses the quality of information available for, and the uncertainties associated with, the assessment.

FDA has determined that this risk assessment is appropriate to the circumstances.



**III. Electronic Access**

The risk assessment is available electronically at <http://www.cfsan.fda.gov>.

Dated: 7/9/04  
July 9, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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