

ACTION: Notice of an evaluation study and request for public comment.

SUMMARY: This notice announces a study to evaluate the effectiveness of Brain Heart Infusion Agar plates containing 6 µg of vancomycin (BHI-V) per ml to detect Vancomycin-resistant *Staphylococcus aureus*.

The CDC would like manufacturers of BHI-V to submit a total of 120 agar plates, 40 plates each of three different lots of BHI-V agar, for testing. The protocol is available on request.

The purpose of this study is to validate the use of BHI-V agar plates, which are currently approved by the Food and Drug Administration in the United States for detecting vancomycin-resistant *Enterococcus* species, for detecting vancomycin-resistant *Staphylococcus aureus*.

DATES: Comments on the CDC Evaluation of Brain Heart Infusion Agar plates containing 6 µg of vancomycin per ml to detect Vancomycin-resistant strains of *Staphylococcus aureus* must be received in writing on or before September 13, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta Carey at (404) 639-3032, e-mail: RCarey@cdc.gov, prior to 4 p.m. on Friday, September 7, 2004.

ADDRESSES: Comments should be submitted to Dr. Roberta Carey, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Healthcare Quality Promotion (C-16), 1600 Clifton Rd., NE., Atlanta, GA 30333, or via e-mail: RCarey@cdc.gov.

SUPPLEMENTARY INFORMATION: Strains of *Staphylococcus aureus* that are resistant to the antimicrobial agent vancomycin pose both clinical and public health concerns. Such strains are difficult to treat and have the potential to spread broadly in healthcare settings causing outbreaks of infection. The first fully vancomycin-resistant isolate of *S. aureus* (VRSA) was isolated from a patient in Michigan in June 2002. A second isolate of VRSA was recovered from a patient in Pennsylvania in September 2002. Unlike the first isolate, resistance in the second isolate was difficult to detect in clinical laboratories using automated antimicrobial susceptibility testing methods. A third VRSA was recovered recently in New York (2004). This isolate also was not detected as fully resistant to vancomycin on initial testing with automated laboratory methods. To enhance the capability to detect VRSA, the CDC proposes that clinical microbiology laboratories inoculate a BHI-V agar plate with colonies of *S.*

aureus, particularly methicillin-resistant strains of *S. aureus*, in conjunction with routine methods of antimicrobial susceptibility testing. Since the BHI-V plate is currently approved by FDA only for use with *Enterococcus* species, the reliability of these commercial media for *S. aureus* needs to be established. The CDC proposes to evaluate, free of charge, all commercially prepared BHI-V currently approved for distribution in the United States. The CDC requests that 120 plates, 40 plates each of 3 different lots of BHI-V agar, be provided to CDC by the manufacturers of these products. The data generated by CDC will be shared with FDA. Those manufacturers who wish to label their product for use with *S. aureus* can request review of these data by contacting Sally Selepek at 301-594-2096 in the Division of Microbiology, FDA. The study is to be initiated on September 13, 2004.

Dated: July 9, 2004.

James D. Seligman,

Associate Director for Program Services,
Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Health and Nutrition Examination Survey (NHANES) Stored Biologic Specimens: Guidelines for Proposals To Use Samples and Proposed Cost Schedule; Correction

A notice and request for comments titled "National Health and Nutrition Examination Survey (NHANES) Stored Biologic Specimens: Guidelines for Proposals To Use Samples and Proposed Cost Schedule" was published in the **Federal Register** on May 24, 2004 (69 FR 29551). This notice is corrected as follows:

On page 29554, third column: the heading "Proposed Cost Schedule for Providing NHANES III DNA Specimen Bank" should now read: "Proposed Cost Schedule for Providing NHANES Stored Biologic Specimens."

Dated: July 5, 2004.

James D. Seligman,

Associate Director for Program Services,
Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0291]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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.