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 Selepak 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.

[FR Doc. 04–15912 Filed 7–13–04; 8:45 am]

BILLING CODE 4163–18–P

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.

[FR Doc. 04–15911 Filed 7–13–04; 8:45 am]

BILLING CODE 4163–18–P

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.

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: July 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15979 Filed 7–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2002–13057]

Carriage of Navigation Equipment for Ships on International Voyages

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy; extension.

SUMMARY: The Coast Guard is extending its policy for resolving conflicts between its own regulations on navigation equipment on ships and the recent amendments to the International Convention for the Safety of Life at Sea, 1974, (SOLAS). The amendments to SOLAS entered into force on July 1, 2002. Until the Coast Guard aligns its regulations with these amendments, this policy should benefit ship owners and operators by relieving them of the need to meet existing Coast Guard regulations that are incompatible with or duplicitous of the new SOLAS requirements.

DATES: This extension of policy is effective July 14, 2004.

ADDRESSES: Documents mentioned in this notice are part of docket USCG–2002–13057 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact LCDR James Rocco, Office of Vessel Traffic Management, U.S. Coast Guard Headquarters, telephone (202) 267–0550; e-mail *jrocco@comdt.uscg.mil.* If you have questions on viewing or submitting material to the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone (202) 366–0271.

SUPPLEMENTARY INFORMATION:

Background

In December 2000, the International Maritime Organization amended chapter V of the International Convention for the Safety of Life at Sea, 1974, (SOLAS) at the 73rd Session of the Maritime Safety Committee. The amendments were accepted by the Contracting Governments to SOLAS on January 1, 2002, and entered into force on July 1, 2002.

These amendments, in part, added requirements for the carriage of voyage data recorders (VDR) and automatic identification systems (AIS), changed the existing tonnage thresholds used to establish carriage requirements for some navigation equipment, and allowed an electronic chart display and information systems (ECDIS) to be accepted as meeting the chart carriage requirements of chapter V. Because of these amendments, the Coast Guard will need to align its regulations in titles 33 and 46 of the Code of Federal Regulations, especially those in 33 CFR part 164, with these amendments. Until this alignment occurs, problems may result because of the inconsistencies between SOLAS chapter V and Coast Guard regulations. For example, if a ship owner elects to install ECDIS, the ship may still be required under 33 CFR 164.33 to carry paper nautical charts.

Policy Statement

Since publishing our initial policy statement on August 15, 2002 (67 FR 53382), we have implemented some SOLAS V amendment regulations. As part of our maritime security regulations, for example, we published an automatic identification system vessel carriage requirement final rule (68 FR 60559, October 22, 2003). But until the Coast Guard aligns all its regulations with the amendments to SOLAS chapter V, the following policy applies:

For ships to which this policy applies, when an amendment to chapter V and a provision in Coast Guard regulations address the same navigational safety concern and when applying both would result in an unnecessary duplication, the Coast Guard will accept the provision under chapter V as meeting the corresponding Coast Guard regulation. In other words, if a ship has an approved ECDIS installed according to chapter V, the ECDIS will be considered by the Coast Guard as meeting its nautical chart regulation in 33 CFR 164.33(a)(1), because the ECDIS meets the same navigational safety concerns as do paper nautical charts. This policy benefits the ship owner and operator by relieving them of the need to unnecessarily duplicate equipment.

Under SOLAS, chapter I, regulation 12, the Coast Guard will not issue SOLAS certificates to U.S.-flag ships that are not in full compliance with the applicable requirements of the new SOLAS, chapter V. The Coast Guard will continue to exercise port state control authority under SOLAS, chapter I, regulation 19, for foreign-flag ships that are not in compliance with the applicable requirements of SOLAS, chapter V. Also, U.S. flag vessels on international voyages, as defined in SOLAS, should be aware that foreign