of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device.

Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on newborn screening test systems for amino acids, free carnitine, and acylcarnitines that utilize tandem mass spectrometry. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry'' by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1301) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–25976 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0479]

Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and is requesting comment on, a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

DATES: Submit written or electronic comments on the draft risk assessment document by January 24, 2005. FDA will accept comments, data, and information after the deadline, but to assure consideration by the agency, we must receive comments by this date.

ADDRESSES: Single copies of this draft risk assessment are available from the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Please enclose a self-addressed, adhesive label to assist that office in processing your request. This draft risk assessment is also available on the Internet at: *http://www.fda.gov/cvm/antimicrobial/antimicrobial.htm*.

Send written comments on this draft risk assessment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

FOR FURTHER INFORMATION CONTACT: Barry Hooberman, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8557, e-mail: *bhooberm@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 19, 2000 (65 FR 20992), FDA's Center for Veterinary Medicine (CVM) announced plans to develop a prototypic risk assessment (RA) model that accounts for the transfer of resistance determinants from bacteria in food-producing animals to bacteria in humans. CVM also requested comments on their approach to the RA model, requested that scientific data and information relevant to the conduct of the RA be submitted, and indicated its intention to work with stakeholders to assess potential risks.

The outcome of our work is a document entitled ''Draft Risk Assessment of Streptogramin Resistance in *Enterococcus faecium* Attributable to the Use of Streptogramins in Animals.'' This draft risk assessment specifically addresses the link between the use of the streptogramin antimicrobial, virginiamycin, in food-producing animals and the development of resistance to the related streptogramins, quinupristin-dalfopristin, used to treat human enterococcal infections. Enterococcus bacteria include commensal strains normally present in the intestines of animals and man. This risk assessment focuses on the opportunistic pathogen *Enterococcus faecium*.

In an effort to better ensure broad awareness of this **Federal Register** notice, FDA will make copies available through the FDA Dockets Listserv (*http://www.fda.gov/ohrms/dockets/FDAMAIL/DMBemaillist.htm*). To be added to any of FDA's free e-mail subscription services go to: *http://www.fda.gov*. Click on ''Subscribe to FDA's E-mail Lists'', then follow the instructions provided.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25979 Filed 11–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board to be held in December 2004.

On December 7, the Board will meet in an open session from 8:30 a.m. to 9:30 a.m. The open session will include a Department of Health and Human Services drug testing program update, a Department of Transportation drug testing program update, and a Nuclear Regulatory Commission drug testing program update. Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

The Board will also meet in closed sessions on December 7 from 9:30 a.m. to 4:30 p.m. and on December 8 from 8:30 a.m. until noon to develop the analytical and administrative policies for the final Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Program that were published as proposed revisions in the **Federal Register** on April 13, 2004 (69 FR 19673). The submissions from 285 commenters have been made available to the public on the Web site *http://workplace.samhsa.gov.* This portion of the meeting must be conducted in closed sessions since discussing such public comments in an open session and then developing the policies will significantly frustrate the Department's ability to develop the Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The HHS Office of General Counsel made the determination that such matters are protected by exemption 9(B) of section 552b(c) of title 5 U.S.C. and therefore may be closed to the public.

A roster of the board members may be obtained from: Mrs. Giselle Hersh, Division of Workplace Programs, 1 Choke Cherry Road, Room 2–1035, Rockville, MD 20857, 240–276–2600 (telephone). The transcript of the open session will be available on the following Web site: *http://workplace.samhsa.gov.* Additional information for this meeting may be obtained by contacting the individual listed below.

Committee Name: Substance Abuse and Mental Health Services, Administration Drug Testing Advisory Board.

Meeting Date: December 7, 2004; 8:30 a.m.–4:30 p.m., December 8, 2004; 8:30 a.m.–Noon.

Place: Residence Inn by Marriott, 7335 Wisconsin Avenue, Bethesda, Maryland 20814.

Type: Open: December 7, 2004; 8:30 a.m.–9:30 a.m., *Closed:* December 7, 2004; 9:30 a.m.–4:30 p.m., *Closed:* December 8, 2004; 8:30 a.m.–Noon.

Contact: Donna M. Bush, Ph.D., Executive Secretary, 1 Choke Cherry Road, Room 2–1035, Rockville, Maryland 20857, Email: *Donna.Bush@samhsa.hhs.gov*, 240–276–2600 (telephone) or 240–276–2610 (fax).

Dated: November 15, 2004.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 04–26025 Filed 11–23–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2004–0023]

Homeland Security Advisory Council

AGENCY: Office of the Secretary, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will hold a meeting for purposes of (1) receiving reports from Senior Advisory Committees; (2) receiving briefings from DHS staff on Departmental initiatives; and (3) holding roundtable deliberations and discussions among HSAC members.

DATES: The Homeland Security Advisory Council (HSAC) will hold its next meeting in San Diego, CA on Tuesday, December 14, 2004.

ADDRESSES: This meeting will be partially closed; the open portions of the meeting for purposes of (1) above will be held at the Westin Horton Plaza Hotel Library, 910 Broadway Circle, San Diego, CA 92101 from 9:30 a.m. to 11:30 a.m. The closed portions of the meeting, for purposes of (2) and (3) above will be held at the Westin Horton Plaza Hotel Harbor Room, 910 Broadway Circle, San Diego, CA 92101 from 8:30 a.m. to 9:20 a.m. and from 11:30 a.m. to 3:30 p.m.