FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

On July 2, 1997, FDA received a petition from bioMerieux Vitek, Inc., requesting reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility devices from class III (premarket approval) to class II (special controls). Based on the petition, a meeting of the Microbiology Devices Panel (the Panel) was convened on February 13, 1998, to obtain the Panel's recommendation on the requested change in classification. The Panel unanimously recommended that fully automated short-term incubation cycle antimicrobial susceptibility devices be reclassified from class III to class II. This guidance document, which takes into consideration the Panel's recommendations and FDA's review experience, would be the special control for the reclassified device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on fully automated short-term incubation cycle antimicrobial susceptibility devices. 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 applicable statute, regulations, or both. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate device must demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternative control that provides equivalent assurances of safety and effectiveness.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive a copy of the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (631) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so 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. Updated on a regular basis, the CDRH home page includes ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' will also be available at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, on or before June 7, 2000, submit to Docket Management Branch (address above) written comments regarding this draft guidance. Two copies of any 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 9, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–5524 Filed 3–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0357]

Draft Guidance for Industry on OTC Treatment of Herpes Labialis With Antiviral Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' Recent interest in marketing antiviral agents over-the-counter (OTC) to treat herpes labialis has raised public health concerns. This draft guidance summarizes the agency's current thinking on why it does not favor the OTC treatment of herpes labialis with antiherpes agents at this time. The guidance also describes issues that sponsors should consider before submitting a marketing application for an OTC antiviral product to treat herpes labialis.

DATES: Submit written comments on the draft guidance by May 8, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at hppt://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph G. Toerner, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''OTC Treatment of Herpes Labialis with Antiviral Agents.'' This draft guidance summarizes the agency's current thinking on the OTC use of antiviral agents to treat herpes labialis. The agency believes that, until other safe

antiherpes agents that lack cross-resistance to the currently available class become available, issues relating to misuse and resistance will need to be thoroughly evaluated in an actual use setting of an antiviral agent for recurrent herpes labialis, particularly if OTC marketing is proposed sometime in the future. At present, based on a public health-based risk/benefit assessment with respect to treatment of herpes labialis, the agency concludes that antiherpes agents should not be made available OTC.

This draft guidance is being issued consistent with FDA's good practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on OTC treatment of herpes labialis with antiviral agents. Its 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 an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–5525 Filed 3–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Small Grants Program for Behavioral Research in Cancer Control.

Date: March 27, 2000.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Olivia T. Preble, Phd, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8052, Rockville, MD 20892–7405, 301/594–2501.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research 93.394, Cancer Detection and Diagnosis Research 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support, 93.398, Cancer Research Manpower, 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 1, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–5657 Filed 3–7–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovative Technologies for the Molecular Analysis of Cancer and their Applications.

Date: March 22–24, 2000.

Time: 7:00 p.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, National Institutes of Health, National Cancer Institute, Special Review, Referral and Resources Branch, 6116 Executive Boulevard, Room 8068, Bethesda, MD 20892, (301) 435–1822.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 1, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–5658 Filed 3–7–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Communication and Interactive Media Technology.

Date: March 23–24, 2000.

Time: 8:00 a.m. to 5:00 p.m.