

identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea P. Latish, Center for Devices and Radiological Health (HFZ-330), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4611.

SUPPLEMENTARY INFORMATION:

I. Background

The SMDA amended section 303(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 333(f)) to authorize FDA to impose CMP actions for all violations of the act involving medical devices except for current good manufacturing practice (CGMP) and medical device report violations that do not constitute a significant or knowing departure from such requirements or a risk to public health, filth violations in devices that are not otherwise defective, and minor violations for tracking and reports of corrections and removals. Thus, FDA has considerable latitude when applying CMP to violations involving devices.

FDA has developed a package of three documents that set forth the agency's policy concerning the application of civil money penalties for violations of the act involving medical devices. The three draft guidance documents are: "Application of the Safe Medical Devices Act Civil Money Penalty Policy," "Safe Medical Devices Act Civil Money Penalty Fee Matrix," and "Safe Medical Devices Act Civil Money Penalty Decision Tree."

The "Application of the Safe Medical Devices Act Civil Money Penalty Policy" outlines the use of the CMP for CGMP and premarket notification (510(k)) violations for chronic and repeat violators, and for less significant violations. It also discusses the relationship between CMP and seizure or injunction. The "Safe Medical Devices Act Civil Money Penalty Decision Tree" outlines whether the evidence and information collected justifies pursuing a CMP case. It is not an all-inclusive list of every issue that should be considered, but rather a series of questions to guide FDA's decision. The "Safe Medical Devices Act Civil Money Penalty Fee Matrix" is a procedure for calculating the penalty amount that will be assessed. The schedule set forth in the matrix covers the statutory factors that FDA is required to evaluate under the SMDA in determining the appropriateness of the case. The matrix will help to ensure consistency in the assessment of a CMP.

FDA is making these three draft guidance documents available to all

FDA Regional and District Directors for the purposes of advising field personnel. FDA is announcing the availability of these documents to the public in order to advise persons who may be affected by FDA's policy and to obtain comment on whether the policy should be revised.

This guidance package of three documents takes into consideration the Presidential Memorandum, dated April 21, 1995, and the Small Business Regulatory Enforcement Fairness Act of 1996, both of which allow monies spent on corrective actions to be deducted from the fine imposed. CMP action, therefore, can provide noncompliant firms with a financial incentive to come into compliance.

The final CMP rule governing the procedures to be used in CMP matters was published in the **Federal Register** of July 27, 1995 (60 FR 38612), and is codified at 21 CFR part 17.

This draft guidance represents the agency's current thinking on the use of CMP recommendations made under the SMDA. 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. This draft guidance is issued as a Level 1 draft guidance consistent with good guidance practices.

II. Electronic Access

In order to receive "Guidance for FDA Staff on Civil Money Penalty Policy" 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 (1124) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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 for FDA Staff on Civil Money Penalty Policy" will be available at "http://www.fda.gov/cdrh/oc".

III. Comments

Interested persons may, on or before September 7, 1999, submit to the Dockets 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 draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 1999.

Linda S. Kahan.

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

[FR Doc. 99-14405 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, June 14, 1999, 7:00 PM to June 16, 1999, 5:00 PM, Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852 which was published in the **Federal Register** on May 20, 1999, 64 FR 27585:

This is not an open meeting. The meeting is closed to the public.

Dated: June 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14502 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Rat Gene Catalog and Expressed Sequence Tag (EST) Map.

Date: June 16, 1999.

Time: 2:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: Teleconference Meeting, 6701 Rockledge Drive, Rm. 9167, Bethesda, MD 20892, (telephone conference call).

Contact Person: Ivan C. Baines, PhD, Scientific Review Administrator, NIH, NHBLI, DEA, Review Branch, Rockledge II, 6701 Rockledge Drive, Suite 7184, Bethesda, MD 20892-7922; 301/435-0277.

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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14500 Filed 6-7-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Pediatric Asthma Clinical Research Network.

Date: June 30, 1999.

Time: 8:00 AM to 5:00 PM.

Agenda: To review and evaluate cooperative agreement applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Anne P. Clark, PhD, NIH, NHLBI, DEA, Review Branch, Rockledge II, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924; (301) 435-0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14501 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

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 meetings.

The meetings 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 Institute of Mental Health Special Emphasis Panel.

Date: June 8, 1999.

Time: 3:00 pm to 4:00 pm.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892 (telephone conference call).

Contact Person: Russell E. Martenson, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd. Rm. 6138, MSC 9696, Bethesda, MD 20892-9696; 301-443-3936.

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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Intervention Research Review.

Date: July 7-9, 1999.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20852.

Contact Person: Lawrence E. Chaitkin, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Blvd. Rm. 6138, MSC 9606, Bethesda, MD 20892-9606; 301-443-6470.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, national Institutes of Health, HHS)

Dated: June 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-14499 Filed 6-7-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: June 10-11, 1999.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Clarion Hampshire Hotel, Washington, DC.