

Dated: April 9, 1996.

Joseph A. Levitt,

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

[FR Doc. 96-17829 Filed 7-12-96; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the Federal Register of June 24, 1996 (61 FR 32443 at 32445). The amendment is being made to announce the cancellation of the third day of the meeting and to change the agenda for the meeting. The location previously announced for the first 2 days remains the same. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT:

For matters relating to electronic fetal monitoring or implantable fetal stents: Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

For matters relating to commercial kits for Group B Streptococcus detection: Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-2096.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 24, 1996, FDA announced that a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee would be held on July 22, 23, and 24, 1996. On page 32445, in the first column, the "Date, time, and place" portion is amended to read as follows:

Date, time, and place. July 22 and 23, 1996, 8:30 a.m., Gaithersburg Marriott Washingtonian Center, Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

On the same page, in the first and second columns, the "Type of meeting and contact person" and "Open committee discussion" portions are amended as follows:

Type of meeting and contact person. Open committee discussion, July 22, 1996, 8:30 a.m. to 2 p.m.; open public hearing, 2 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 7 p.m.; open committee discussion, July 23, 1996, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 3 p.m.; open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 6:15 p.m.; Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Obstetrics and Gynecology Devices Panel, code 12524. Please call the hotline for information concerning any possible changes.

Open committee discussion. On July 22, 1996, the committee will be asked to consider new technological advances in intrapartum electronic fetal monitoring (EFM). After hearing a series of presentations on the subject, the committee will discuss appropriate recommended testing for such new technology applications. FDA will consider these recommendations in the future development of testing guidelines. Committee deliberations on this subject will continue on July 23, 1996. FDA recognizes that there continues to be questions asked about EFM and its place in the clinical management of the patient in labor. The intent of the committee discussion is not to resolve issues related to clinical practice and clinical standards in the area of EFM. Rather, the focus of discussions will be on reasonable study methodologies for establishing the safety and effectiveness of the new fetal monitoring technologies. On July 23, 1996, following the discussions on new technological advances in intrapartum EFM, the committee will discuss and vote on a premarket approval application (PMA) for an implantable stent used for in utero treatment of fetal post-vesicular uropathy. Also, on July 23, 1996, following deliberations on the above PMA, the committee will discuss issues concerning the performance of commercial kits for the direct detection of Group B Streptococcus from clinical specimens obtained from pre-term and intrapartum women, and neonates, in relation to the kits' indications for use.

Dated: July 3, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-17828 Filed 7-12-96; 8:45 am]

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National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Notice is hereby given of the meeting of the National Center Institute Board of Scientific Advisors Prevention Program Working Group, August 21, 1996 at The DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland.

The meeting will be closed to the public from 12 p.m. to adjournment for discussion of confidential issues relating to the review, discussion and evaluation of individual programs and projects conducted by the NCI Prevention Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Information pertaining to the meeting may be obtained from Dr. Jack Gruber, Executive Secretary, National Center Institute Prevention Program Working Group, National Cancer Institute, 6130 Executive Blvd., EPN, Rm. 540, Bethesda, MD 20892 (301-496-9740).

Dated: July 9, 1996.

Margery G. Grubb,

*Senior Committee Management Specialist,
NIH.*

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BILLING CODE 4140-01-M

National Cancer Institute; Notice of Closed Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors Cancer Centers Program Working Group, July 22, 1996 at the Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, VA.

This meeting will be closed to the public from 8:30 am to adjournment for discussion of confidential issues relating to the review, discussion and evaluation of individual programs and projects conducted by the Cancer Centers Extramural Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and