A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 14, 1996, file with the Docket Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in the brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–17825 Filed 7–12–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96M–0200]**

## Bayer Corp.; Premarket Approval of Technicon Immuno 1® PSA Assay

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Bayer Corp., Tarrytown, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Immuno 1® PSA Assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 22, 1995, of the approval of the application.

**DATES:** Petitions for administrative review by August 14, 1996.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1293.

**SUPPLEMENTARY INFORMATION:** On June 27, 1995 Bayer Corp., Tarrytown, NY 10591, submitted to CDRH an application for premarket approval of Immuno 1® PSA Assay. This device is an in vitro diagnostic device intended to quantitatively measure prostate specific antigen (PSA) in human serum on the Technicon Immuno 1® system. PSA values obtained should be used as an aid in the management (monitoring) of prostate cancer patients. This diagnostic method is not intended for use on any other system.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory Committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On December 22, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 14, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

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]

**BILLING CODE 4160–01–F**

## 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.*

[FR Doc. 96–17890 Filed 7–12–96; 8:45 am]

**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