Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040.

Dated: October 2, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 96–25874 Filed 10–8–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96M–0356]

American Medical Systems, Inc.; Premarket Approval of UroLume™ Endourethral Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by American Medical Systems, Inc., Minnetonka, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the UroLume™ Endourethral Prosthesis. After reviewing the recommendation of the Gastroenterology and Urology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 6, 1996, of the approval of the application.

DATES: Petitions for administrative review by November 8, 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: James P. Seiler, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1195.

SUPPLEMENTARY INFORMATION: On June 14, 1993, American Medical Systems, Inc., Minnetonka, MN 55343, submitted to CDRH an application for premarket approval of the UroLume™ Endourethral Prosthesis. The device is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3 centimeters in length located distal to the external sphincter and proximal to the bulbar scrotal junction. The UroLume™ Endourethral Prosthesis is not intended as an initial treatment for bulbar urethral strictures nor for the treatment of strictures outside the bulbar urethra. The UroLume™ Endourethral Prosthesis is an alternative treatment for the patient in whom previous treatment methods (e.g., dilation, urethrotomy, or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease, or there has been recurrence of stricture formation necessitating further treatment).

On January 20, 1995, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On May 6, 1996, 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 (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 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 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 November 8, 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: September 20, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–25877 Filed 10–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0358]

EDAP Technomed Group (U.S.A.), Inc.; Premarket Approval of Prostatron™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by the EDAP Technomed Group (U.S.A), Inc., Cambridge, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Prostatron™. After reviewing the recommendation of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 3, 1996, of the approval of the application.

DATES: Petitions for administrative review by November 8, 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: John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION: On April 17, 1995, the EDAP Technomed Group

(U.S.A.), Inc., Cambridge, MA 02139, submitted to CDRH an application for premarket approval of the Prostatron™. The device is a transurethral microwave thermal therapy system and is indicated as a nonsurgical treatment alternative to transurethral resection of the prostate (TURP) for the treatment of symptomatic benign prostatic hyperplasia (BPH). The Prostatron™ is indicated for patients with prostatic lengths of 35 to 50 millimeters. It is intended that the Prostatron™ deliver a complete thermal therapy treatment during a single treatment session.

On October 20, 1995, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On May 3, 1996, 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 (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 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 November 8, 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: September 20, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–25878 Filed 10–8–96; 8:45 am]

BILLING CODE 4160–01–F

International Conference on the Virological Safety of Plasma Derivatives; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a public meeting that will address the risks posed by blood-borne viruses that persist in human plasma-derived products. CBER is sponsoring the meeting with the National Heart, Lung, and Blood Institute of the National Institutes of Health, the Centers for Disease Control and Prevention, The World Health Organization, and the International Association of Biological Standards. The goals of the meeting include assessing the virological safety of currently available plasma-derived products and gathering information useful in the evaluation of such products.

DATES: The meeting will be held on November 20, 21, and 22, 1996, from 8:30 a.m. to 5 p.m. Preregistration is requested by November 8, 1996. Registration at the site will be done on a space-available basis on each day of the public meeting beginning at 8 a.m.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Natcher Conference Center, Main Auditorium, Bldg. 45, 9000 Rockville Pike, Bethesda, MD.

FOR FURTHER INFORMATION CONTACT:

For information concerning the meeting: Thomas J. Lynch, Center for Biologics Evaluation and Research (HFM–340), Food and Drug Administration, 8800 Rockville Pike, rm. 311, Bethesda, MD 20892–001, 301–496–6890.

For information concerning registration and agenda for the meeting: Viral Safety '96, KRA Corp., 1010 Wayne Ave., Silver Spring, MD 20910, 301–495–1591. Fax registration to 301–443–9410, including name, title, firm name, address, and telephone number. There is no registration fee for this meeting, but advance registration is recommended because seating is limited to about 700.

SUPPLEMENTARY INFORMATION: FDA has the responsibility for helping to ensure that plasma derivatives pose as little risk as possible to those who depend on them. The safety of plasma-derived therapeutic proteins is also an important global public health issue. Recently, considerable progress has been made in developing improved methods for screening plasma derivatives for the presence of viruses. Advances made in detecting viruses have been accompanied by improvements in viral inactivation and removal procedures. Nevertheless, current risks of transmitting blood-borne viruses through the use of products derived from human plasma have not been fully eliminated, and there are concerns about future, unknown risks. The goal of this meeting is to exchange views and information regarding the present and future safety of these products. To achieve this goal interested members of the medical, research, industry, regulatory, and patient communities are invited to attend the meeting to hear an international group of experts present their experiences and recommendations concerning the virological safety of plasma derivatives. Topics to be covered include: Virology and epidemiology, testing for viral markers, developments in viral detection, techniques and validation of viral inactivation and removal, manufacturing practices and safeguards, validation of viral safety, nonenveloped viruses, transmissible spongiform encephalopathies, and surveillance and response. Information presented at this meeting will assist the sponsoring and participating public health agencies to evaluate the current virological safety of plasma derivatives and to determine what future action may be appropriate.