(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.

Dated: October 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–26040 Filed 10–8–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–72]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Information Collection Requirements in 42 CFR 473.18 (a) and (b), 473.34 (a) and (b), 473.36 (a) and (b), and 473.42 (a), Peer Review Organization (PRO) Reconsideration and Appeals ; *Form No.:* HCFA–R–72; *Use:* These regulations contain procedures for PRO's to use in reconsideration of initial determinations. The information requirements contained in these regulations are on PROs to provide information to parties requesting a reconsideration review. These parties will use the information as guidelines for appeal rights in instances where issues are still in dispute; *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 53; *Total Annual Responses:* 15,670; *Total Annual Hours:* 3,578.

2. *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Request for Enrollment in Supplementary Medical Insurance; *Form No.:* HCFA–4040; *Use:* The HCFA–4040 is used to establish entitlement to Supplementary Medical Insurance by Beneficiaries not eligible under Part A of Title XVIII or Title II of the Social Security Act. The HCFA–4040SP is the Spanish edition of this form; *Frequency:* One time only; *Affected Public:* Individuals and households, Federal government, State, local, or tribal governments; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 2,500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Certification as a Rural Health Clinic, Rural Health Clinic Survey Report Form; *Form No.:* HCFA–29, 30; *Use:* The form HCFA–29 ''Request for Certification as a Rural Health Clinic'' is used by facilities to apply to participate in the Medicare program. The form HCFA–30 ''Rural Health Clinic Survey Report Form, is used by State survey agencies to record data needed to determine compliance with the Federal requirements; *Frequency:* Annually; *Affected Public:* State , local or tribal governments; *Number of Respondents:* 390; *Total Annual Responses:* 390; *Total Annual Hours:* 682.

4. *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Quarterly Showing; *Form No.:* HCFA–R–41; *Use:* This form is used by State Medicaid agencies to list participating health care facilities and the dates the State agencies reviewed the facilities. The lists are required to assure the existence of an effective utilization (of services) control program, as required by law and regulation, to avoid a penalty; *Frequency:* Quarterly; *Affected Public:* State, local or tribal governments; *Number of Respondents:* 47; *Total Annual Responses:* 188; *Total Annual Hours:* 9,212.

5. *Type of Information Collection Request:* Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection:* Quarterly Showing Validation Survey; *Form No.:* HCFA–9050; *Use:* Reporting entities may be required to submit lists of Medicaid beneficiaries residing in a select number of institutions. State Medicaid agencies may also be required to submit procedures for conducting inspection of care reviews and other documentation necessary to validate the Quarterly Showing reports. The listings are required to determine those patients for which the State is currently responsible for their care. This part of the operation to determine that states have an effective utilization control program; *Frequency:* Annually; *Affected Public:* State, local or tribal governments; *Number of Respondents:* 47; *Total Annual Responses:* 8; *Total Annual Hours:* 376.

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Business Proposal Formats for Utilization and Quality Control Peer Review Organizations (PROs); *Form No.:* HCFA–718–721; *Use:* Submission of proposal information by current PROs and other bidders, according to the business proposal instructions, will satisfy HCFA's need for consistent, and verifiable data with which to validate contract proposals; *Frequency:* Other (Tri-annually); *Affected Public:* Business or other for profit, not for profit institutions; *Number of Respondents:* 20; *Total Annual Responses:* 23; *Total Annual Hours:* 450.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: October 2, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–25833 Filed 10–8–96; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on