is an immunoradiometric assay intended for the quantitative measurement of prostate-specific antigen (PSA) in serum to aid in the management of prostate cancer patients.

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 September 15, 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 October 15, 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

Dated: August 30, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–23408 Filed 9–11–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–190]

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, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. 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.

Type of Information Collection Request: New collection; *Title of Information Collection:* Hospital Standard for Potentially HIV Infectious Blood and Blood Products; *Form No.:* HCFA-R–190; *Use*: Hospitals must establish policies/procedures and document patient notification efforts if they have administered potentially HIV infectious blood and blood products. *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 16; *Total Annual Responses:* 16; *Total Annual Hours Requested:* 16.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain 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 must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 5, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff Office of Financial and Human Resources

[FR Doc. 96–23381 Filed 9–11–96; 8:45 am]

BILLING CODE 4120–03–P

[HCFA–588, 43, 116, 668A]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal 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 a previously approved collection for which approval has expired; *Title of Information Collection:* Authorization Agreement for Electronic Funds Transfer; *Form No.:* HCFA–588; *Use:*

This information is needed to allow providers to receive funds electronically in their bank. *Frequency:* On occasion; *Affected Public:* Business or other for profit, not for profit institutions; *Number of Respondents:* 78,550; *Total Annual Hours:* 9,819.

2. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Application of Health Insurance Under Medicare for Individuals with Chronic Renal Disease; *Form No.:* HCFA–43; *Use:* This form is used as a standard method of eliciting information necessary to determine entitlement to Medicare under the end stage renal disease provision of the law. *Frequency:* On occasion; *Affected Public:* Individuals and households, Federal government; *Number of Respondents:* 80,000; *Total Annual Hours:* 34,400.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments Application Form; *Form No.:* HCFA–116; *Use:* This application is completed by entities performing laboratory testing on human specimens for health purposes. *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal Government, and State, Local or Tribal Governments; *Number of Respondents:* 16,000; *Total Annual Hours:* 20,000.

4. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Post Laboratory Survey Questionnaire-Surveyor; *Form No.:* HCFA–668A; *Use:* This survey provides the surveyor with an opportunity to evaluation the survey process. The form is completed in conjunction with the HCFA form 668B. This information will help HCFA evaluate the entire survey process from the surveyor's prospective. *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal Government, and State, Local or Tribal Governments; *Number of Respondents:* 1,560; *Total Annual Hours:* 390.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov , or to obtain 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 must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance 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.

Date: September 4, 1996.

Edwin J. Glatzel,

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

[FR Doc. 96–23327 Filed 9–11–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Eye Institute; Notice of the Meeting of the National Advisory Eye Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Eye Council (NAEC) on September 12, 1996, Executive Plaza North, Conference Room G, 6130 Executive Boulevard, Bethesda, Maryland.

The NAEC meeting will be open to the public on September 12 from 8:30 a.m. until approximately 11:30 a.m. Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs and policies. Attendance by the public at the open session will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the NAEC will be closed to the public on September 12 from approximately 11:30 a.m. until adjournment at approximately 5:00 p.m. for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Lois DeNinno, Council Assistant, National Eye Institute, EPS, Suite 350, 6120 Executive Boulevard, MSC–7164, Bethesda, Maryland 20892–7164, (301) 496–9110, will provide a summary of the meeting, roster of committee members, and substantive program information upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. DeNinno in advance of the meeting.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistant Program No. 93.867, Vision Research: National Institutes of Health)

Dated: September 9, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–23563 Filed 9–11–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. FR–4126–D–01]

Designation

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of designation.

SUMMARY: This notice designates the Office of Lead-Based Paint Abatement and Poisoning Prevention, located in the Office of the Secretary, as the Office of Lead Hazard Control.

EFFECTIVE DATE: August 29, 1996.

FOR FURTHER INFORMATION CONTACT: David E. Jacobs, Director of the Office of Lead Hazard Control, Department of Housing and Urban Development, 451 7th Street, S.W., Washington, D.C. 20410, (202) 755–1785, ext. 102. (This is not a toll-free number.) For hearing- and speech-impaired persons, this number may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Under HUD's Appropriations Act for 1992, enacted in 1991, Congress required the establishment of an ''Office of Lead-Based Paint Abatement and Poisoning Prevention'' located in the Office of the Secretary of the Department of Housing and Urban Development. The Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act of 1992, at 105 Stat. 753 (Pub. L. 102–139, October 28, 1991).

Subsequently, under the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851 *et seq.*), Congress broadened considerably the scope of HUD's responsibilities for lead-based paint beyond abatement. Under