Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104–191). Subtitle F of Title II of HIPAA, entitled ''Administrative Simplification,'' (A.S.) requires the Secretary of Health and Human Services to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to ''covered entities'' referred to in section 1320d–2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA A.S. Transactions, Code Sets, Identifiers and Security Rules has been delegated to the Centers for Medicare & Medicaid Services; *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit, Individuals or Households; Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.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 to the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, PRA Analyst, Room C5–13–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 27, 2005.

Michelle Shortt,

Acting Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–11136 Filed 6–2–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10156]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 this 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed. It is critical that the Medicare Retiree Drug Subsidy (RDS) applications be available to plan sponsors on August 1, 2005 in order for there to be enough time for the RDS Center to process the applications.

Under Section 1860D–22 of the Social Security Act, added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR 423.880 plan sponsors (employers, unions etc.) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. Plan sponsors must submit a complete application to CMS in order to be considered for the RDS program.

CMS is requesting OMB review and approval of this collection by July 4, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 3, 2005.

Type of Information Collection Request: New Collection.

Title of Information Collection: Retiree Drug Subsidy (RDS) Application and Instructions.

Use: Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implementing regulations at 42 CFR Subpart R plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to CMS with a list of retirees for whom it intends to collect the subsidy.

Form Number: CMS–10156 (OMB#: 0938–NEW).

Frequency: Quarterly, Monthly, Annually.

Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government.

Number of Respondents: 50,000.

Total Annual Responses: 50,000.

Total Annual Hours: 2,025,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/regulations/pra* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by July 3, 2005:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5–13–27, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–

0262. Attn: Melissa Musotto, CMS–10156;
and,
OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 1, 2005.

Jimmy Wickliffe,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–11178 Filed 6–2–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005M–0005]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from October 1, 2004, through December 31, 2004. There were no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE OCTOBER 1, 2004, THROUGH DECEMBER 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 040046/02005M–0005	Bio-Rad Laboratories	Multispot HIV–1/HIV–2 Rapid Test	November 12, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cber/products.htm*.

Dated: April 11, 2005.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 05–11072 Filed 6–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.