

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/prs/>, 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.

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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/prs/> 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]

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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.