waivers to states to provide pharmacy benefits to low-income elders with incomes too high to qualify for Medicaid. This study will evaluate the Pharmacy Plus programs initiated in the states of Illinois and Wisconsin using a variety of methods including a descriptive program evaluation, survey of participants, analyses of drug utilization and costs as well as the cost impact to the Medicare and Medicaid programs.

Frequency: Other: one-time only.

Affected Public: Individuals or Households.

Number of Respondents: 2,200.

Total Annual Responses: 2,200.

Total Annual Hours: 550.

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://cms.hhs.gov/regulations/pra/default.asp,* 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: June 12, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 03–15827 Filed 6–23–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10094]

Agency Information Collection Activities: Proposed Collection; Comment Request

Agency: Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (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.

Type of Information Collection Request: New Collection.

Title of Information Collection: Evaluation of the Medicaid Health Reform Demonstrations.

Form No.: CMS–10094 (OMB# 0938–NEW).

Use: This survey is part of an evaluation of the State of Vermont's pharmacy assistance programs, which principally serve low income Medicare beneficiaries who do not have other coverage for prescription drugs. The surveys will explore the issues of self-selection into the pharmacy programs, motivations for joining or not joining, the extent of pharmacy coverage among low income Medicare beneficiaries who are not enrolled and the impact of coverage on Medicare spending. The Vermont evaluation is part of a larger evaluation of section 1115 Medicaid demonstration programs in five states. (The other states are California, Kentucky, Minnesota and New York. The survey will take place only in Vermont.)

Frequency: Other: One-time.

Affected Public: Individuals or Households.

Number of Respondents: 11,310.

Total Annual Responses: 11,310.

Total Annual Hours: 1,087.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* 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 directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 12, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Strategic Affairs.

[FR Doc. 03–15828 Filed 6–23–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on August 20, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, (301)827-7001, e-mail: *TurnerT@cder.fda.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 ((301)443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss clinical trial design issues in the development of topical microbicides for the reduction of HIV transmission.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 13, 2003. Oral presentations from the public will be

scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited.

Those desiring to make formal oral presentations should notify the contact person before August 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 13, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–15890 Filed 6–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0231]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This specific guidance discusses issues related to the electronic submission of postmarketing periodic adverse drug experience reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), and therapeutic and blood products marketed for human use with biologics license applications (BLAs). This guidance does not apply to vaccines, whole blood or components of whole blood. The submission of these reports in electronic format will significantly improve the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written or electronic comments on the draft guidance by August 25, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, Levinr@cder.fda.gov; or Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM–588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, (301)827-5132, *Fauntleroy@cber.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports.'' A postmarketing periodic adverse drug experience report includes individual case safety reports (ICSRs), attachments to ICSRs (ICSR attachments), if applicable, and descriptive information. The descriptive information includes the narrative summary and analysis of the information in the report, an analysis of the 15-day alert reports submitted during the reporting interval, and the history of actions taken since the last report because of adverse drug experiences (e.g., labeling changes, studies initiated).

This draft guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports. It provides guidance on the submission of periodic ICSRs, ICSR attachments, and descriptive information in electronic format. Applicants are referred to the draft guidance for industry ''Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports'' (May 2001) for details on submitting periodic ICSRs and ICSR attachments to FDA.[1] Applicants are also referred to the guidance for industry ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (January 1999) for details on submitting the descriptive information to FDA on physical media.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing postmarketing periodic adverse drug experience reports in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for marketed human drug and biological products is already covered by the collection of

[1]FDA is considering comments from the public on this draft guidance for industry and plans to issue a final guidance on this topic in the future.