notice will have no consequential effect on State, local, or tribal governments. We believe the private sector costs of this notice will fall below this threshold as well.

In accordance with Executive Order 13132, this notice will not significantly affect the rights of States and will not significantly affect State authority.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 1865(b)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(b)(3)(A)).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 7, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–27782 Filed 10–31–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: DHHS/ACF Rural Welfare-to-Work Strategies Demonstration Evaluation Project 18-Month Survey.

OMB No.: New Collection.

Description: the Rural Welfare-to-Work Strategies Demonstration Evaluation Project, which was developed and funded by the Administration for Children and Families (ACF) of the U.S. Department of Health and Human Services (HHS), is a national evaluation to determine the benefits and cost-effectiveness of methods designed to aid current or former Temporary Assistance for Needy Families (TANF) recipients or other low-income families as they transition from welfare to the employment arena. This evaluation chiefly attempts to address four research questions:

- What are the issues and challenges associated with operating the new welfare-to-work services and policy approaches being studied?
- How effective are the welfare-to-work programs under the project in increasing employment and earnings and in improving other measures?
- What are the net costs of the welfare-to-work programs, and do the programs' benefits outweigh the costs?
- What approaches should policymakers and program managers consider in designing strategies to improve the efficacy of welfare-to-work strategies for families in rural areas?

The evaluation employs a multi-pronged approach to answer the research questions. These approaches include: (1) An impact study, which will examine the differences between control and intervention groups with respect to factors such as employment rates, earnings, and welfare receipt; (2) a cost-benefit analysis, which will calculate estimates of net program cost-effectiveness; and (3) an in-depth process study, which will identify implementation issues and challenges, examine program costs, and provide details on how programs achieve observed results. The data collected during the conduct of this study will be used for the following purposes:

- To study rural welfare-to-work programs' effects on factors such as employment, earnings, educational attainment, family composition;
- To collect data on a wider range of outcome measures—such as job acquisition, retention, and advancement, job quality, educational attainment, and employment barriers—than is available through welfare or unemployment insurance records, in order to understand how individuals are being affected by the demonstration programs;
- To support research on the implementation of welfare-to-work programs across sites;
- To obtain program participation and service use information important to the evaluation's cost-benefit component; and
- To obtain contact information for a future follow-up survey that will be important to achieving high response rates for that survey.

Respondents: The respondents of the 18-month follow-up survey are current and former TANF recipients, or individuals in families at risk of needing TANF benefits (working poor, hard-to-employ) from the three states participating in the evaluation (Illinois, Nebraska, and Tennessee). The survey will be administered to both intervention and control groups in each participating site. The estimated sample size for the survey is 3,400 individuals, including projected samples of 2,200 in Tennessee, and 600 each in Illinois and Nebraska. The survey will be conducted primarily by telephone, with field interviews conducted with those individuals who cannot be interviewed by telephone.

Respondents of the process study data collection efforts (interviews, case studies, and focus groups) include State and local-level agency staff from welfare agencies and other organizations. These individuals include program directors and site managers, program line staff, workforce development staff, TANF agency staff, and community partners and employers. Approximately 105 staff members per site are expected to participate in semi-structured interviews, 21 in case conferences, and 108 in focus groups, across the three demonstration sites.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
18-Month Follow-up Survey	963	1	45 minutes or .75 hours	723
Process Study Data Collection Staff Interviews	105	1	75 minutes or 1.15 hours	120.8
Process Study Data Collection Staff Case Conferences	21	1	30 minutes or .5 hours	10.5
Process Study Data Collection Staff Focus Groups	108	1	90 minutes or 1.5 hours	162

Estimated Total Annual Burden Hours: 1016.3.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration Office of Information Services, 370 L'Enfant Promenade, SW., Washington,

DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 23, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–27759 Filed 10–31–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Women's Health Initiative Subcommittee of the Advisory Committee for Reproductive Health Drugs; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Women's Health Initiative Subcommittee of the Advisory Committee for Reproductive Health Drugs scheduled for November 12 and 13, 2002. The meeting was announced in the **Federal Register** of October 21, 2002 (67 FR 64651). FDA's Center for Drug Evaluation and Research is going to evaluate additional data relevant to the topic. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, or e-mail: *PETERSONJ@CDER.FDA.GOV*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Dated: October 24, 2002.

LaJuana D. Caldwell,

Acting Senior Associate Commissioner for External Relations.

[FR Doc. 02–27884 Filed 10–31–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0427]

Guidance for Industry on Antiretroviral Drugs Using Plasma Human Immunodeficiency Virus Ribonucleic Acid Measurements—Clinical Considerations for Accelerated and Traditional Approval; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, this guidance addresses the agency's current thinking regarding designs of clinical trials that use HIV ribonucleic acid (RNA) measurements to support accelerated and traditional approvals of antiretroviral drug products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Murray, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of HIV infection. Specifically, this guidance addresses the agency's current thinking regarding designs of clinical trials that use HIV RNA measurements to support accelerated and traditional approvals of antiretroviral drug products. It is also intended to serve as a focus for continued discussions among the Division of Antiviral Drug Products (DAVDP), pharmaceutical sponsors, the academic community, and the public.

The draft version of this document, first issued in August 1999, was based on a DAVDP advisory committee meeting, convened in July 1997, to discuss the use of HIV RNA endpoints for traditional approval of antiretroviral drugs. This document has been updated to address public comments to the draft version and to include pertinent information from a DAVDP advisory committee meeting held in January 2001 that addressed issues relating to trial design in HIV-infected patients who have already been heavily treated for the disease. The guidance summarizes the rationale for using HIV RNA as a primary endpoint in clinical trials to support both accelerated and traditional approval. It describes the amount and type of safety and efficacy data recommended for new drug applications. The guidance also reviews pertinent clinical trial design issues including choice of control arms, study procedures, and statistical considerations. An appendix addresses the use of experimental HIV RNA assays in phase 3 studies.

This guidance does not address specific phase-1 and -2 development issues, development of alternate dosing regimens, or the use of HIV–1 resistance testing. These issues will be addressed in separate future guidance documents.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical considerations for accelerated and