4,360; *Total Annual Responses:* 4,360; *Total Annual Hours:* 34,880.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification, P.L. 95–292; 42 CFR 405.2133; 45 CFR 5, 5b; 20 CFR Parts 401, 422E; *Form No.:* CMS–2746 (OMB# 0938–0448); *Use:* The ESRD Death Notification is to be completed upon the death of ESRD patients. Its primary purpose is to collect fact and cause of death. Reports of deaths are used to show cause of death and demographic characteristics of these patients; *Frequency:* Other: One-time (patient death); *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal Government; *Number of Respondents:* 4,360; *Total Annual Responses:* 69,760; *Total Annual Hours:* 34,880.

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@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 OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 7, 2003.

Julie Brown,

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

[FR Doc. 03–28710 Filed 11–17–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Privacy Act of 1974; Deletion of Systems of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS).

ACTION: Notice to delete 3 systems of records.

SUMMARY: CMS proposes to delete 3 systems of records from its inventory subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

EFFECTIVE DATES: The deletions will be effective on November 3, 2003.

ADDRESSES: The public should address comments to: Director, Division of Privacy Compliance Data Development (DPCDD), CMS, Room N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

SUPPLEMENTARY INFORMATION: Whenever the Centers for Medicare & Medicaid Services (CMS), proposes to modify or delete an SOR, we are required by the Privacy Act to publish a notice in the **Federal Register** and provide a period of time during which the public may comment. We must also report the proposed action to the Office of Management and Budget (OMB) and Congress.

CMS is deleting from its inventory of Systems of Records the records listed below because they are no longer needed. The projects have ended. Records will be disposed of in accordance with a National Archive and Records Administration (NARA) approved schedule.

Systems To Be Deleted

System No. 09–70–0045, ''Evaluation of the Arizona Health Care Cost Containment & LTC Systems Demo (EAHCCC),'' HHS/CMS/ORDI;

System No. 09–70–0049, ''Evaluation of the HHA Prospective Payment Demo (EHHAPD).''

HHS/CMS/ORDI; System No. 09–70–0063, ''Evaluation of the Medicaid Demo for Improving Access to Care for Substance Abusing Pregnant Women,'' HHS/CMS/ORDI.

Dated: November 3, 2003.

Thomas A. Scully,

Administrator.

[FR Doc. 03–28719 Filed 11–17–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: HHS/ACF Rural Welfare-to-Work Strategies Demonstration Evaluation Project 30-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 addresses 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, and 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 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 to the 30-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 two states participating in the evaluation (Illinois and Nebraska). The survey will be administered to both intervention and control groups in each participating site. The estimated sample size for the survey is 984 individuals, including projected samples of 504 in Illinois and 480 in Nebraska. The survey will be conducted primarily by telephone, with field interviews conducted with those individuals who cannot be interviewed by telephone. OMB already approved the process evaluation component and 18-month follow-up survey for this study.

Note: Tennessee has been dropped from the study due to difficulties in recruiting participants to their program. Therefore, the estimated burden is smaller than the one in the first notice.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of esponses per respondent	Average burden hours per response	Total burden hours
30-month follow-up survey	246	1	30 minutes or .5 hours	123

Estimated Total Annual Burden Hours: 123

Additional Information: Copies of the proposed collection may be obtained 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. E-mail address: *rsargis@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *lauren__wittenberg@omb.eop.gov.*

Dated: November 10, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–28759 Filed 11–17–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0300]

Determination That Diclofenac Potassium 25-Milligram Tablet Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that diclofenac potassium 25-milligram (mg) tablet (Cataflam) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diclofenac potassium 25-mg tablet.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness § 314.62 (21 CFR 314.162)). Regulations also provide that the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On June 27, 2003, The Weinberg Group, Inc., submitted a citizen petition (Docket No. 2003P–0300/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether diclofenac potassium 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Diclofenac potassium 25-mg tablet is the subject of NDA 20–142, approved in 1993 and held by Novartis Pharmaceuticals Corp. (Novartis). Diclofenac potassium is used for the treatment of osteoarthritis and rheumatoid arthritis. FDA has determined that shortly after the approval of NDA 20–142, Novartis made the decision not to market diclofenac potassium 25-mg tablet in the United States. It was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. FDA has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is