## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

**Proposed Projects**

*Title:* Head Start Program Information Report (PIR).

*OMB No.:* 0980–0017.

*Description:* The Head Start Act requires that actual population and services data be collected from Head Start and Early Head Start grantees and delegate agencies. The Head Start Program Information Report (PIR) is the primary tool for collecting information in the areas of program management, services provided, and the demographics of the children enrolled and their families. The principle users of the data include local program management, ACF Regional Office staff, and ACYF Central Office staff. The information is disseminated widely to other interested parties, including Congress, policy makers at the State level, training and technical assistance providers, and researchers.

*Respondents:* Head Start grantees and delegate agencies; Early Head Start grantees and delegate agencies.

*Annual Burden Estimate:*

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| PIR | 2437 | 1 | 4 | 9748 |

*Estimated Total Annual Burden Hours:* 9748.

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 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: May 22, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01–13317 Filed 5–25–01; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* Study of the TANF Application Process.

*OMB No.:* New Collection.

*Description:* The Study of the TANF Application Process is designed to provide systematic information about how application policies and processes have changed under TANF, and how States define and count applications and application results. The Study will also explore how application policies are implemented in a sample of local TANF offices and will collect data on individuals' application decisions, experiences, and outcomes. In addition, the Study will also collect information on the availability and quality of State-collected data on the TANF application process. The primary purpose of this Study is to provide useful information to be considered in the upcoming TANF reauthorization process and provide applicant information as required by 42 U.S.C. 611(b)(2).

*Respondents:* The respondents for the Mail Questionnaire are the 50 States, the District of Columbia, and the U.S. Territories of Guam, Puerto Rico, and the Virgin Islands. Eighteen States will be respondents to the State Telephone Survey, 54 individuals for the Open-ended Interviews for Case Studies, six States for Case Abstractions, and 1200 individuals for the Follow-up Telephone Interviews with Applications and Non-applicants.

*Annual Burden Estimates:*

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| 18-State Telephone Survey | 18 | 1 | 3 | 54 |
| 54-State Mail Questionaire | 54 | 1 | 6 | 324 |
| Open-ended interview for Case Studies | 54 | 1 | 1.5 | 81 |
| Follow-up Telephone Interview with Applicants and Non-applicants | 1200 | 1 | .33 | 396 |
| Case abstractions-pulling case files for contractor review and abstraction | 6 | 1 | 20 | 120 |
| Estimated Total Annual Burden Hours | | | | 975 |

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

*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, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: May 22, 2001.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 01–13318 Filed 5–25–01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0231]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements obligating holders of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to submit information on adverse drug reactions, lack of effectiveness, and product defects.

**DATES:** Submit written or electronic comments on the collection of information by July 30, 2001.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA, (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506 (c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2) (A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed reinstatement of an existing collection before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510 (OMB Control No. 0910–0012)—Extension**

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)), 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved NADAs submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format.

This continuous monitoring of approved new animal drugs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians also using FDA forms 1932 and 1932a. FDA form 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Form No. | 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|---|
| Form FDA 2301 | 510.302(a) | 190 | 13.16 | 2,500 | 0.5 | 1,250 |
| Form FDA 1932 | 510.302(b) | 190 | 94.74 | 18,000 | 1.0 | 18,000 |