

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* April 2004 Current Population Survey Supplement on Child Support.

OMB No.: 0992-0003.

*Description:* Collection of the data will assist legislators and policymakers in determining how effective their policymaking efforts have been over time in applying the various child support legislation to the overall child support enforcement picture. This information will help policymakers determine to what extent individuals on

welfare would be able to leave the welfare rolls as a result of more stringent child support enforcement efforts.

*Respondents:* Individuals and households.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Support Survey .....	47,000	1	.0246	1156
Estimated Total Annual Burden Hours: .....				1156

*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. All requests should be identified by the title of the information collection. E-mail address: [rsargis@acf.hhs.gov](mailto: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](mailto:lauren_wittenberg@omb.eop.gov).

Dated: January 8, 2003.

**Robert Sargis,**

*Reports Clearance Office.*

[FR Doc. 04-775 Filed 1-13-04; 8:45 am]

BILLING CODE 4184-0-M

President on November 18, 2003. This act amends the Federal Food, Drug, and Cosmetic Act, and authorizes FDA to collect four types of user fees: Application fees, establishment fees, product fees, and sponsor fees. Before FDA can begin collecting these fees, enabling appropriations must be enacted. Until further notice, such fees should not be submitted to FDA. However, sponsors should continue to submit new animal drug applications as in the past until additional direction is provided. Certain types of applications submitted on or after September 1, 2003, will be subject to fees, but an invoice for those fees will not be issued until after enabling appropriations are enacted. FDA will publish another **Federal Register** notice specifying fee amounts and procedures for submitting payments.

**ADDRESSES:** Visit the FDA Web site that provides further information on ADUFA at: <http://www.fda.gov/oc/adufa>.

**FOR FURTHER INFORMATION CONTACT:** Robert Miller, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-5436; e-mail: [rmiller2@cvm.fda.gov](mailto:rmiller2@cvm.fda.gov). For general questions, you may also contact the Center for Veterinary Medicine at: [mailto:cvmadufa@fda.gov](mailto:mailto:cvmadufa@fda.gov).

**SUPPLEMENTARY INFORMATION:** ADUFA authorizes FDA to collect fees for: (1) Certain types of animal drug applications and supplemental animal drug applications submitted on or after September 1, 2003, (2) certain animal drug products, (3) certain establishments where such products are manufactured in final dosage form, and (4) certain sponsors of animal drug applications or investigational animal drug submissions. However, FDA may not begin to collect these fees until enabling appropriations are enacted. After the enactment of enabling

appropriations, FDA will publish a **Federal Register** notice with detailed payment procedures.

For FY 2004 through FY 2008, ADUFA establishes overall fee revenue amounts for application fees, establishment fees, product fees, and sponsor fees. Revenue amounts established for years after FY 2004 are subject to annual adjustments for inflation and workload. Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that revenues will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. FDA will publish a **Federal Register** notice with the FY 2004 fee rates and detailed payment instructions.

In an effort to better ensure broad awareness of interim procedures relating to ADUFA, FDA has established a Web site that provides further information at <http://www.fda.gov/oc/adufa>.

Dated: January 7, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-812 Filed 1-13-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Animal Drug User Fee Act of 2003; Interim Procedures**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing interim procedures relating to the Animal Drug User Fee Act (ADUFA) of 2003, which was signed by the

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Number 2003D-0558]

**Draft Compliance Policy Guide, Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability; and Draft Supporting Document, Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Guidance Levels for Radionuclides in Domestic and Imported Foods." The draft CPG would rescind and replace the current CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14). The draft CPG provides updated guidance levels for radionuclide activity concentration in food offered for import and makes these same guidance levels for radionuclide activity concentration applicable to food in domestic interstate commerce for the first time. The draft CPG also expands the scope of coverage of FDA policy from food accidentally contaminated with radionuclides to food accidentally or intentionally contaminated with radionuclides. The agency is also announcing the availability of a draft supporting document entitled "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods."

**DATES:** Submit written or electronic comments concerning the draft CPG and/or the draft supporting document by March 15, 2004.

**ADDRESSES:** Submit written requests for single copies of the draft CPG entitled "Guidance Levels for Radionuclides in Domestic and Imported Foods" and/or the draft supporting document entitled "Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods" to Paul South (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document. Submit written comments on the draft CPG and/or draft supporting document 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>.

**FOR FURTHER INFORMATION CONTACT:** Paul South, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1640, fax: 301-436-2651, e-mail: [psouth@cfsan.fda.gov](mailto:psouth@cfsan.fda.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA has developed a draft CPG to rescind and replace CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14)

concerning radionuclides in food. While CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14), which was issued in 1986 following the Chernobyl nuclear accident, only addresses radionuclides in food offered for import, this draft CPG is intended to provide clear policy and regulatory guidance to FDA's field and headquarters staff with regard to radionuclides in both food offered for import and domestic food in interstate commerce. In particular, the draft CPG sets forth new guidance levels for radionuclides, referred to as Derived Intervention Levels (DILs). FDA would use DILs to help determine whether food in interstate commerce or food offered for import into the United States presents a safety concern. The DILs adopted in the draft CPG are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against food with concentrations below the DILs or decide not to initiate an enforcement action against food with concentrations that meet or exceed the DILs. The scientific basis for the DILs established in the draft CPG is presented in the draft supporting document. The draft CPG also contains information that may be useful to the regulated industry and to the public.

The agency has adopted good guidance practices (GGPs) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR § 10.115). The draft CPG is being issued as a Level 1 draft guidance consistent with GGPs. The draft CPG represents the agency's current thinking on its enforcement process concerning the adulteration of foods with radionuclides. It does not create or confer any rights for or on any person and does not operate to bind FDA, or the public.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft CPG and the draft supporting document. Submit a single copy of electronic comments 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. Received comments, the draft CPG, and the draft supporting document may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the draft CPG and the draft supporting document at <http://www.fda.gov/ora> under "Compliance References."

Dated: January 7, 2004.

**John M. Taylor,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 04-719 Filed 1-13-04; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of Inspector General****Agency Information Collection Activities (OIG-319-FN)**

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this notice sets forth the Office of Inspector General's summary of collection activities with regard to State Medicaid Fraud Control Units' Recertification Application and Annual Reports, as required by 42 CFR 1007.15 and 1007.17 of the OIG regulations. A proposed notice of these information collection activities was published for public comment in the March 26, 2003 edition of the **Federal Register** (68 FR 14668). No public comments were received in response to that proposed collection activities notice.

**SUPPLEMENTARY INFORMATION:**

*Type of Information Collection Request:* Reinstatement of an expired collection.

*Title of Information Collection:* State Medicaid Fraud Control Units' Recertification Application and Annual Report as required by 42 CFR 1007.15 and 1007.17. (Previously approved by the Office of Management and Budget under control number 0990-0162.)

*Use:* The information contained in the annual reports and recertification application is required for certification and yearly recertification by the OIG to ensure that federal matching funds are only expended for allowable costs, and to determine if a State unit needs technical assistance.

*Frequency:* Annually.

*Affected Public:* State government.

*Annual Number of Respondents:* 48.

*Total Annual Responses:* 48.

*Average Burden Per Response:* 32 hours.

*Total Annual Hours:* 2,744 hours.