

SPRING 2006—Continued

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Classroom Staff: Complete Parallel Teacher-Reported Ratings .....	180	8	1/4	360
Head Start Lead Teacher: Complete Feedback Survey on Teacher-Reported Rating Measures .....	180	1	1/12	15
<b>Field Test of Modifications to Current HSNRS Direct Child Assessment Battery</b>				
Head Start Staff: Administer Modified Measures .....	60	24	1/4	360
Head Start Children: Participate in Modified Measures .....	1,440	1	1/4	360
<b>Field Test of Collection of Child Health Information</b>				
Head Start Staff: Collect & Submit Child Health Info .....	30	48	1/12	120
Head Start Staff: Demonstrate Procedures for collecting Height and Weight Information .....	30	1	1/6	5
Head Start Staff: Complete Feedback Survey on Child Health Data Collection Procedures .....	30	1	1/12	2.5
Spring 2006 Totals .....	3,000	.....	.....	2,155
Grand Totals .....	3,000	.....	.....	4,580

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. E-mail: [rsargis@acf.hhs.gov](mailto:rsargis@acf.hhs.gov).

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: August 17, 2005.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 05-16640 Filed 8-22-05; 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:* Application Requirements for the Low Income Home Energy

Assistance Program (LIHEAP) Model Plan.

OMB No.: 0970-0075.

*Description:* The 1994 reauthorization of the LIHEAP statute, the Human Services amendments of 1994 (Public Law 103-252, requires that States, including the District of Columbia, Tribes, Tribal organizations and territories applying for LIHEAP block grant funds must submit an annual application (Model Plan) that meets the LIHEAP statutory and regulatory requirements prior to receiving Federal funds. A detailed application must be submitted every three years. Abbreviated applications may be submitted in alternate years. There have been minor changes in the Model Plan for clarity. There have been no substantive changes.

*Respondents:* State, local or tribal governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Detailed Model Plan .....	65	1	1	65
Abbreviated Model Plan .....	115	1	.33	38

*Estimated Total Annual Burden Hours:* 103.

*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: [grjohnson@acf.hhs.gov](mailto:grjohnson@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: [Katherine\\_T.\\_Astrich@omb.eop.gov](mailto:Katherine_T._Astrich@omb.eop.gov).

Dated: August 16, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 05-16641 Filed 8-19-05; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0153]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 22, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Regulations For In Vivo Radiopharmaceuticals Used For Diagnosis and Monitoring—(OMB Control Number 0910-0409)—Extension**

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), FDA published a final rule (64 FR 26675, May 17, 1999) amending its regulations by adding provisions that clarify FDA's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the act and the PHS Act. The information, which is usually submitted as part of a new drug application (NDA), biologics license application, or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an

application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (OMB control number 0910-0001, approved by OMB until March 31, 2005). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. The burden totals do not include an increase in burden. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000