

security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A-130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

**RETENTION AND DISPOSAL:**

CMS will retain identifiable MSIS data for a total period not to exceed 10 years after the final determination of the case is completed. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Informational Analysis and Technical Assistance,

Finance, Systems & Budget Group, Center for Medicaid and State Operations, CMS, Mail Stop S3-18-15, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**NOTIFICATION PROCEDURE:**

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

**RECORD ACCESS PROCEDURE:**

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2).)

**CONTESTING RECORDS PROCEDURES:**

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7.)

**RECORDS SOURCE CATEGORIES:**

CMS obtains the identifying information contained in this system from state Medicaid agencies, or Medicaid Management Information Systems maintained by the individual states, and information contained on CMS Form 2082.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review, Comment Request**

*Title:* Evaluation of the Head Start Region III I am Moving, I am Learning (IM/IL) Program.

*OMB No.:* New Collection.

*Description:* The purpose of this evaluation is to examine the implementation of the Head Start project I am Moving, I am Learning (IM/IL) as a preventive intervention targeting obesity in children. IM/IL was designed to fit within the Head Start Performance Standards and the Head Start Child Outcomes Framework through enhancements to current teaching and family support practices by providing more focused guidance on quality movement, gross and fine motor development, and child nutrition.

This data collection will be conducted among programs implementing IM/IL in Region III, and will gain information about each site's program context and service components, including level of adoption of IM/IL enhancements, intensity of implementation, and sustainability of enhancements. Progress toward achieving outcomes and goals of the IM/IL program that can be measured will also be assessed.

*Respondents:* Head Start directors, management teams, teachers, and staff in Region III that received spring 2006 IM/IL training; parents or guardians of children who attend Head Start programs where IM/IL is being implemented.

**ANNUAL BURDEN ESTIMATES**

| Instrument                                     | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Director/Manager Questionnaire .....           | 65                    | 1                                  | 0.84                              | 54.6               |
| Director/Manager Telephone Interview .....     | 30                    | 1                                  | 1.5                               | 45.0               |
| Teacher/Home Visitor Telephone Interview ..... | 60                    | 1                                  | 0.5                               | 30.0               |
| Director Interview .....                       | 16                    | 1                                  | 2.0                               | 32.0               |
| Key Management Staff Interview .....           | 48                    | 1                                  | 1.5                               | 72.0               |
| Teacher/Home Visitor Focus Group .....         | 80                    | 1                                  | 1.5                               | 120.0              |
| Parent Focus Group .....                       | 160                   | 1                                  | 1.5                               | 240.0              |

*Estimated Total Annual Burden Hours:* 593.6.

*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: [infocollection@acf.hhs.gov](mailto:infocollection@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, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: [Karen\\_T.\\_Matsuoka@omb.epo.gov](mailto:Karen_T._Matsuoka@omb.epo.gov).

Dated: November 3, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006N-0435]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes**

**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 extending OMB approval on the existing

reporting requirements for the information collection activity entitled “How to Use E-mail to Submit a Notice of Intent to Slaughter For Human Food Purposes.”

**DATES:** Submit written or electronic comments on the collection of information by January 8, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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, Jr., Office of the Chief Information Officer (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 extension of an existing collection of information, 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 these topics: (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.

**Guidance for Industry on “How to Use E-mail to Submit a Notice of Intent to Slaughter for Human Food Purposes,” Section 512j, Federal Food, Drug, and Cosmetic Act; (OMB Control Number 0910-0450)—Extension**

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act), gives FDA the authority to set conditions under which animals treated with investigational new animal drugs may be marketed for food use. Under this authority, the Center for Veterinary Medicine (CVM), issues to a new animal drug sponsor (sponsors) a slaughter authorization letter that sets the terms under which investigational animals may be slaughtered. The United States Department of Agriculture (USDA), also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601-95). Sponsors must submit slaughter notices each time investigational animals are presented for slaughter, unless this requirement is waived by an authorization letter ((21 CFR 511.1(b)(5)), (9 CFR 309.17)). These notifications assist CVM and USDA in monitoring the safety of the food supply. Slaughter notices were previously submitted to CVM and USDA on paper. (OMB No. 0910-0450). CVM’s guidance on “How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes” provides sponsors with the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the internet.

The electronic submission of slaughter notices is part of CVM’s ongoing initiative to provide a method for paperless submissions.

The likely respondents are new animal drug sponsors.

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

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

| Form No.       | No. of Respondents | Annual Frequency per Response | Total Annual Responses <sup>2</sup> | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|-------------------------------------|--------------------|-------------|
| FDA Form #3488 | 25                 | .08                           | 2                                   | 0.41               | .82         |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.