DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF–HS–93600–97–03–1]

Administration on Children, Youth and Families; Early Head Start Program Grant Availability

AGENCY: Administration on Children, Youth and Families, ACF, DHHS.

ACTION: Correction notice.

SUMMARY: This notice corrects the announcement of the availability of financial assistance and request for applications for the Early Head Start program, published in the **Federal Register** on April 17, 1997. Five of the geographic areas noted in Appendix D of the announcement under funding Category One are being changed.

FOR FURTHER INFORMATION CONTACT: Mireille Kanda (202) 205–8308.

SUPPLEMENTARY INFORMATION: On April 17, 1997, the Administration for Children and Families published in the **Federal Register** a notice which announced the availability of funds for competing applications for Early Head Start (62 FR 18966–19005). The purpose of this program is to provide early, continuous, intensive, and comprehensive child development and family support services on a year-round basis to low-income families with children under age three and pregnant women.

Geographic Areas

Georgia

The original citation of the ''Counties of Dekalb, Scottsdale and Decatur'' should be changed to ''Within Dekalb County the communities of Scottsdale, Decatur and that section of Atlanta in Dekalb County.''

Michigan

The original citation of ''Menominee, Delta and Schoolcraft Counties'' should be changed to ''Delta County.''

Texas

The original citation of ''Northeast Dallas'' should be changed to ''Southeast Dallas.''

Utah

Originally we listed Box Elder and Cache Counties in Utah and Franklin County in Idaho as served areas. This should be corrected. These counties are deleted from the list of served areas and are open now for competition under Category I.

Wisconsin

Originally the Counties of Barron, Chippewa, Dunn, Pepin, Pierce, Polk, and St. Croix were listed as served areas. This should be corrected. These counties are deleted from the list of served areas and are open now for competition under Category I.

Dated: May 15, 1997.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97–13552 Filed 5–22–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0201]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 pursuant to the Paperwork Reduction Act of 1995 (the PRA). This notice solicits comments on a data collection effort consisting of four consumer surveys regarding preferences for, and comprehension of information contained in different formats and methods for communication in over-the-counter (OTC) drug labels. For two of these studies (studies A and B), the agency has requested emergency processing of the proposed collection by the Office of Management and Budget (OMB).

DATES: Submit written comments on the collection of information for studies A and B by June 2, 1997. Submit written comments on the collection of information for studies C and D by July 22, 1997.

ADDRESSES: Submit written comments on the collection of information for studies A and B to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. Submit written comments on the collection of information for studies C and D to the Dockets Management Branch (HFA–305), ATTN: OTC Drug Labeling Data Collection, Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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, rm. 16B–19, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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 before submitting the collections to OMB for approval. Section 3507(j) of the P.A. and 5 CFR 1320.12 provides for emergency processing of proposed collection of information.

FDA intends to conduct four separate studies related to the labeling of OTC drug products. For studies A and B, the agency is requesting emergency processing because the information is necessary for the agency's deliberations on a proposed rule related to providing easier to read and easier to understand labeling on OTC drug products. (See 62 FR 9024.) The agency has determined that there is a public health need for revised OTC labeling, which is essential to the agency's mission, and if normal clearance procedures were followed, it would take longer to conclude the related OTC labeling rulemaking.

To comply with the PRA requirements, FDA is publishing notice of the proposed collections of information listed below.

With respect to the following collections of information, FDA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimates of the burdens of the proposed collections 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 burdens of the collections of information on respondents, including through the use of automated collection

techniques, when appropriate, and other forms of information technology.

1. Evaluation of Proposed OTC Label Formats and OTC Label Format Preference

Under sections 201(n) and 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 321(n) and 352), FDA has the authority to ensure that approved drugs are properly labeled. Section 201(n) of the act defines a drug as misbranded if its labeling or advertising is misleading; this includes the failure to reveal material facts. Under section 903 of the act (21 U.S.C. 393), FDA may conduct research related to drugs and conduct educational and public information programs relating to the responsibilities of the FDA. FDA will evaluate proposed OTC label formats and study the effect of various label formats on consumers' preference. The agency will conduct two studies:

In study A (Evaluation of Proposed OTC Label Formats), consumers will be shown the label of an OTC drug using either the proposed or the traditional format. Based on the different labels and different reading conditions, consumers' knowledge, attitudes, and decisions about proper drug use will be investigated.

In study B (OTC Label Format Preference), consumers will be asked to view examples and variations of current OTC label designs. Respondents will be asked to indicate their preference for various designs, as well as demonstrate memory retention of labeling information. Also, consumers will be asked to evaluate labeling terminology and graphics to investigate how they interpret various ways of communicating drug safety and effectiveness.

2. Evaluation of Statement of Identity Comprehension and of Alcohol Warning Statement Comprehension

Under sections 201(n) and 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 321(n) and 352), FDA has the authority to ensure that approved drugs are properly labeled. Section 201(n) of the act defines a drug as misbranded if its labeling or advertising is misleading; this includes the failure to reveal material facts. Under section 903 of the act (21 U.S.C. 393), FDA may conduct research related to drugs and conduct educational and public information programs relating to the responsibilities of the FDA. FDA will study the comprehension of the statement of identity and warning information on labeling for OTC drug products. FDA will conduct two studies:

In study C (Statement of Identity Comprehension), consumers will be asked to view examples and variations of the placement of OTC statement of identity information. Respondents will be asked to demonstrate their perceptions and reactions to placement of active ingredient(s), pharmacologic category, and/or intended action information on the front and/or back portion of the product package.

In study D (Alcohol Warning Statement Comprehension), consumers will be asked to rate the clarity or understandability of the warning message. Respondents will be asked to rate various methods of conveying the alcohol warning that systematically vary the specificity, permissiveness, frequency, and quantity descriptors in the alcohol warning messages.

In each of the four studies, participants will examine materials varied by one or more format or content variables. Central location intercept sites that are geographically dispersed will be used to recruit and question respondents.

FDA estimates the burden of these collections of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
A & B	2,100	1	2,100	.5	1,050
C & D	480	1	480	.5	240

There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13601 Filed 5–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms—0915–0043—Extension, No Change

This clearance request is for extension of approval for 3 HEAL forms: the Repayment Schedule is used by lenders to inform the borrower of the cost of a HEAL loan, the number and amount of payments, and the Truth-in-Lending requirements; the Promissory Note is used by the lender to provide the borrower with the legally binding terms of the loan; and the Lender's Report (also known as the Call Report) is used by the lender to provide the Department with information on the status of all loans outstanding. The forms are needed to provide borrowers with information on their responsibilities and to determine which lenders may have