

Dated: May 3, 2002.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02091]

National Programs To Support Healthy Aging, Epilepsy, Prevention Activities, and Arthritis; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for National Programs to Support Healthy Aging, Epilepsy, Prevention Activities, and Arthritis. These programs address the "Healthy People 2010" focus areas of Access to Quality Health Services, Educational and Community Based Programs, Physical Activity and Fitness, Disability and Secondary Conditions, Arthritis, Osteoporosis, and Chronic Back Conditions, and Health Communication.

The CDC, National Center for Chronic Disease Prevention and Health Promotion, is issuing this Program Announcement in an effort to simplify and streamline the grant and cooperative agreement pre-award and post-award administrative process, provide increased flexibility in the use of funds, and measure performance related to each grantee's stated objectives. Some advantages of the streamlined process are: elimination of separate documents (continuation application and semi-annual progress report) to issue a continuation award; consistency in reporting expectations; and increased flexibility within approved budget categories.

This program announcement covers the following program areas:

Program Area 1: Healthy Aging

The purpose of the Healthy Aging Program is to establish national partnerships to enhance health and quality of life for older adults through a broad national strategy to: (1) Promote oral, physical, and mental health healthy behaviors, (2) reduce the impact of injuries and chronic diseases, and (3) maintain function and independence for older Americans. Applicants may apply for one or more of the following priority areas:

Priority A—Collaboration and Health Promotion: To strengthen and enhance collaborations between health departments at the state and local level, and/or community organizations/networks that focus on older adults, e.g. senior centers and area agencies on aging, to promote behaviors and practices that lead to healthier, more fulfilling, and more satisfying lives for older adults.

Priority B—Implementation and Evaluation: To strengthen the capacity of national, state, and/or local agencies to conduct and evaluate programs that promote health, reduce the impact of injuries and chronic diseases, and maintain function and independence for older adults.

Priority C—Evaluate and Develop Tools: To assess and develop consumer education tools and strategies to improve health, reduce the impact of disease and injury, and delay disability and the need for long-term care among older adults.

Program Area 2: Epilepsy

The purpose of this program is to conduct epilepsy programs that enhance the health and quality of life of people with epilepsy through health promotion, education and enhancement of communication channels. Applicants may apply for one or more of the following priority areas:

Priority A—Partnership Building: To promote public awareness of epilepsy and facilitate collaborative partnerships at all levels of public health.

Priority B—Create Awareness/Improve Health Communications: To expand the outreach of media campaigns to promote understanding and awareness and improve communication strategies to develop, disseminate, and evaluate epilepsy educational materials and programs.

Priority C—Consumer and Provider Education: To expand the availability of carefully designed and well tested low-literacy epilepsy education materials for minority groups, self-management materials for those with epilepsy, and continuing medical education for health care providers.

Program Area 3: Prevention Activities

The purpose of this program is to develop national health promotion and disease prevention strategies for health care organizations, state and local health departments, businesses, and other non profit organizations whose mission is to promote prevention, improve health care quality and improve the public's health.

Program Area 4: Arthritis

The purpose of the Arthritis program is to implement the National Arthritis Action Plan: A Public Health Strategy (NAAP). Specific activities are intended to improve the availability and quality of information and services in order to improve the quality of life for persons with arthritis.

B. Eligible Applicants

Assistance will be provided only to existing grantees under the following program announcements:

a. National Programs to Support Healthy Aging—Program Announcement 01133.

b. Initiatives to Develop and Implement Programs to Enhance Epilepsy, Public Awareness and Partnerships, Education, and Communication—Program Announcement 01134.

c. Implementation of the National Arthritis Action Plan: A Public Health Strategy—Program Announcement 99128.

d. National Strategies to Promote Disease Prevention and Health Promotion—Program Announcement 99153.

Attachment I at the end of this document contains a sole source justification for the Arthritis Foundation. **Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

C. Availability of Funds

Program Area 1: Healthy Aging

Approximately \$500,000 is available in FY 2002 to fund five awards. The average award will be \$100,000, with a range from \$75,000 to \$200,000.

Priority Area A—Collaboration and Health Promotion: Approximately \$100,000 is available to fund one award under Priority Area A in FY 2002.

Priority Area B—Implementation and Evaluation: Approximately \$200,000 is available to fund two awards under Priority Area B in FY 2002. The average award is expected to be \$100,000.

Priority Area C—Evaluating and Developing Tools: Approximately \$200,000 is available to fund two awards under Priority Area C in FY 2002. The average award is expected to be \$100,000.

Program Area 2: Epilepsy

Approximately \$2,100,000 is available in FY 2002 to fund one award.

Program Area 3: Prevention Activities

Approximately \$500,000 is available in FY 2002 to fund one award.

Program Area 4: Arthritis

Approximately \$1,000,000 is available in FY 2002 to fund one award.

Note: It is expected that all awards under this Program Announcement will be awarded on or before August 30, 2002 and will be made for a 12-month budget period. It is expected that Program Areas 1 and 2 (Healthy Aging and Epilepsy) will have project periods of up to five years; Program Areas 3 and 4 (Prevention Activities and Arthritis) are expected to have project periods of up to two years. Funding estimates may change due to availability of funds.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for conducting the activities under 1. (Recipient activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

*1. Recipient Activities**Program Area 1: Healthy Aging*

Priority Area A—Collaboration and Health Promotion: Develop mechanisms to:

a. Provide resources to health departments at the state and local level and/or community organizations/networks that focus on promoting healthy behaviors and practices among older adults.

b. Develop communications resources for use by communications organizations and older adults.

c. Develop tools to help communities inventory and publicize their resources.

d. Integrate health plans and other health care resources into community demonstration projects.

Priority Area B—Implementation and Evaluation:

a. Identify innovative health and supportive programs for older adults;

b. Conduct systematic review and synthesis of quality programs including organizational capacity, resource requirements and outcomes achieved;

c. Disseminate findings to organizations and individuals who work in the field of aging studies.

Priority Area C—Evaluate and Develop Tools: Evaluate existing consumer education tools and strategies and develop new tools by:

a. Conducting consumer research and marketing activities (e.g. focus groups and other appropriate assessment

activities) among older adults, including those from minority and other underserved communities.

b. Developing recommendations and strategies for group-specific future interventions, educational messages, and programs according to the findings.

Program Area 2: Epilepsy

The applicant shall conduct activities in one or more of the following three priority areas:

Priority Area A—Partnership Building:

a. Provide financial and personnel support to epilepsy affiliates/chapters and other health-related organizations to facilitate building collaborative public health partnerships with state and local health departments.

b. Provide financial and personnel support to health related organizations (other than epilepsy affiliates/chapters) to facilitate building collaborative partnerships.

c. Expand ongoing communication vehicles (i.e., listservs, web sites, newsletters, conference calls, meetings) to facilitate problem solving and idea sharing among organizations involved in collaborative activities to strengthen programs to promote public awareness of epilepsy, provide education for those with epilepsy, the general public, and for health care providers, and enhance communication channels.

Priority Area B—Create Awareness/Improve Health Communications:

a. Expand a sustained multifaceted media relations outreach program.

b. Expand, implement and evaluate strategies to disseminate existing educational materials to those with epilepsy who are under served.

Priority Area C—Consumer and Provider Education

a. Expand the development or adaption, evaluation, and dissemination of low-literacy epilepsy education materials and/or educational materials for under served segments of the population, including large minority groups (e.g., Hispanic, Asian, American Natives, African American).

b. Develop, evaluate, and disseminate epilepsy self-management materials delivered through traditional and/or alternative delivery mechanisms (i.e., Internet-based, CD ROM, other).

c. Develop appropriate training on selected epilepsy interventions with demonstrated cost-effectiveness with appropriate experts including international organizations.

d. Develop, evaluate, and disseminate continuing medical education (CME) or CME and continuing education units (CEU) granting self study professional education through alternative delivery

mechanisms (i.e., Internet based, CD-ROM).

Program Area 3: Prevention Activities

a. Develop and implement national health disease prevention programs and preventive health models for use by the recipient in providing assistance to a broad range of organizations, including private sector health care organizations, State and local health departments, universities, managed care organizations, and businesses.

b. Collaborate nation-wide with public, private, nonprofit, and academic institutions to promote the goals of prevention.

c. Conduct process and outcome evaluation on all activities.

d. Disseminate information concerning effective prevention activities for health care organizations.

Program Area 4: Arthritis

The applicant should propose at least one activity in each of the two following areas:

Priority Area A—Partnership Activities

a. Develop mechanisms to provide financial support to Arthritis Foundation Chapters to participate in collaborative activities with state health department and other partners.

b. Develop mechanisms to support training for Arthritis Foundation Chapter staff, state and local health department staff, and others to provide evidence-based self management education and physical activity programs (i.e., Arthritis Self Help Course—ASHC, People with Arthritis Can Exercise®—PACE, and Arthritis Foundation Aquatics).

Priority Area B—Consumer education

a. Based on the results of evaluation activities funded in FY 2000 and FY 2001, further develop, evaluate, and disseminate self-management materials delivered through web-based or CD ROM delivery mechanisms. Applicant is strongly encouraged to review the adequacy of previous or ongoing evaluation efforts and propose new or expanded efforts as necessary.

b. Support evaluation activities that may include market research approaches to better characterize the use and non-use of evidence-based self management education (i.e., ASHC) or physical activity (i.e., PACE or Aquatics) programs. Specifically, this activity should (1) characterize program participants and non-participants, specifically addressing access and availability issues, and demographic characteristics; (2) examine current strategies for program dissemination and access; (3) identify factors,

facilitators and barriers, that limit or enhance the delivery and utilization of programs; and (4) recommend strategies to improve program delivery to significantly improve the utilization of the programs.

c. Support evaluation activities to determine the effectiveness of existing Arthritis Foundation self management education or physical activity interventions. The grantee is strongly encouraged to examine these interventions among large minority groups. The ASHC should not be considered under this activity.

d. Develop mechanisms to enhance the capacity of the Arthritis Foundation to respond to requests for information from the public.

e. Develop or support the development of innovative self management education or physical activity programs. These programs should have clearly defined purposes and objectives. Newly developed programs should be pilot tested in preparation for a more thorough evaluation. They should not be disseminated prior to evaluation. No more than \$100,000 should be devoted to this activity. The grantee may conduct this activity through AF chapters.

f. Support or develop mechanisms to support training for leaders and trainers for the Spanish language version of the Arthritis Self Help Course.

g. Identify new opportunities to partner in the development of new health communications messages and materials. Hard to reach, underserved populations, especially African Americans and Hispanic Americans are of special interest.

2. CDC Activities for Program Areas 1, 2, 3, and 4 (Healthy Aging, Epilepsy, Arthritis and Prevention Activities)

a. Provide consultation on potential activities and mechanisms of fulfillment for partnership support, including chapters or affiliates and other partners. CDC will provide careful review of applicant grant announcements and where appropriate, participate in the review of applications.

b. Provide consultation on health communication and education efforts for the public in general, older adults, people with arthritis and people with epilepsy. CDC will provide review and input on the scope of work for proposed activities.

c. Provide consultation on the development and evaluation of self management education, physical activity, or other prevention programs. CDC will work with recipients to ensure proposed activities complement work

already supported or conducted by CDC and are consistent with a public health approach to address arthritis, epilepsy, and older adults.

d. Provide consultation and support to analyze and interpret data from evaluation activities.

e. Provide assistance to plan and implement linkages among agencies funded under this program announcement. CDC will work to explore synergies among the activities of the different agencies funded under this announcement.

f. Provide assistance in the dissemination of interventions and training materials. CDC's support of and ongoing interaction with state health departments and other partners provide a mechanism for dissemination of evaluated health communication and self management materials developed under this announcement.

E. Content

Application

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated using the criteria listed, so it is important to follow them in laying out your program plan. All applications should have a type-written narrative of no more than 20 double-spaced pages, printed on one side, with one inch margins and 12 point Times New Roman font. The application should be organized into the following sections:

1. Executive Summary

Provide a clear, concise, and objectively written statement of the major objectives and components of the proposed activities, proposed time frame, and evaluation plan. Include proof of your non-profit status.

2. Needs Assessment

Describe the documented need for the proposed activities and current activities that provide relevant experience and expertise to perform the proposed activities.

3. Collaborative Relationships

Describe collaborative relationships with other agencies and organizations that will be involved in the proposed activities.

4. Operational and Evaluation Plan

Describe the specific process, impact, and outcome objectives for each proposed project, the major steps required to achieve the objectives, and a projected timetable for completion that displays dates for the

accomplishment of specific proposed activities. Describe the evaluation process that will be used to determine effectiveness and initiate improvement as needed.

5. Management and Staffing Plan

Describe how the program will be effectively managed. Include the following:

a. Management structure including the lines of authority and plans for fiscal control.

b. The staff positions responsible for implementation of the program.

c. Qualifications and experience of the designated staff.

6. Budget and Justification

Provide a detailed budget request and line item justification of all proposed operating expenses.

F. Submission and Deadline

Applications

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are available at the internet address: <http://www.cdc.gov/od/pgo/forminfo.htm> or in the application kit. Submit the application on or before July 1, 2002 to: Technical Information Management—PA02091, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Room 3000, Atlanta, GA 30341-4146.

Deadline: Applications shall be considered as meeting the deadline if they are received on or before the deadline date.

Late Applications: Applications which do not meet the criteria above are considered late applications, and will be returned to the applicant.

G. Evaluation Criteria (100 Points)

Applications received from grantees funded under Program Announcements 01133, 01134, 99128, or 99153 will be reviewed by independent reviewers utilizing the Technical Acceptability Review (TAR) process.

1. Needs Assessment: (25 points)

The extent to which the applicant demonstrates that the experience and expertise for the proposed projects.

2. Collaboration: (15 points)

The extent to which the applicant provides evidence of collaborative relationships with other agencies and organizations relevant to successful completion of the proposed projects.

3. Operational and Evaluation Plan: (35 points)

The extent to which the applicant clearly identifies the specific outcome and process objectives for the proposed projects, and the major steps required to meet the objectives; provides a realistic plan for collaboration with partners including CDC in the project; and proposes an evaluation plan that is likely to provide meaningful information about the achievement of the project's objectives.

4. Implementation Plan: (10 points)

The extent to which the projected timetable for completion of tasks and for meeting objectives is reasonable and realistic.

5. Project Management and Staffing Plan: (15 points)

The extent to which the applicant demonstrates management structure and staff positions with clear lines of authority and plans for fiscal control, and that designated staff have appropriate qualifications and experience.

6. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and justification consistent with the proposed program objectives and activities.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. *Semi-annual progress reports.* The first report is due February 28, 2003. Subsequent semi-annual reports will be due on the 28th of February each year through February 28, 2006.

Continuation Application Guidance:

The February 28 semi-annual progress report and accompanying budget and budget justification will be used to process your continuation award. Semi-annual progress reports should include the following information outlined in the requirements under items (a) through (e):

a. A succinct description of the program accomplishments/narrative and progress made in meeting each program objective during the first six months of the budget period (August 30 through February 28) and should consist of no more than 20 pages.

b. The reason for not meeting established program goals and strategies to be implemented to achieve unmet objectives (see performance measures attached for each program area).

c. A description of any new objectives including the expected impact on the

overall burden of cardiovascular diseases and related risk factors and method of evaluating effectiveness.

d. A one year line item budget and budget justification.

e. For all proposed contracts, provide the name of contractor, period of performance, method of selection, method of accountability, scope of work, and itemized budget and budget justification. If the information is not available when the application is submitted, please indicate *to be determined* until the information is available. When the information becomes available, it should be submitted to the CDC Procurement and Grants Management Office contact identified in this program announcement. Documenting and reporting the number of training programs offered and the number of people trained.

2. *Annual progress reports.* The annual report is due no more than 90 days after the end of the budget period (August 30, 2003) and should consist of the same information outlined for the semi-annual progress report in (a) through (c) above.

3. Financial status reports are due, no more than 90 days after the end of the budget period.

4. Final financial and performance reports are due, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Measures of Effectiveness

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the Program and Priority areas as stated below. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

Program Area 1: Healthy Aging

Priority Area A—Collaboration and Health Promotion: Document the change in healthy behavior of aging adults by developing resources that focus on promoting healthy behaviors and practices among older adults: documentation should include a description of the process used, the scientific rationale for the content of the resources, intended target audience, and proposed evaluation plans.

Priority Area B—Implementation and Evaluation: Review of programs for older adults and dissemination of findings: documentation should include a description of the evaluation and dissemination processes.

Priority Area C—Evaluation and Development of Tools:

Evaluate current consumer educational tools and develop new tools: Documentation should include a description of the evaluation and development processes.

Program Area 2: Epilepsy

1. Develop diverse and active partnerships: documentation should include materials (i.e., minutes of meetings that delineate partners' roles, lists of work group members, outcomes or products of partnerships, communication vehicles developed or expanded to facilitate idea sharing among partners) that demonstrate collaboration on epilepsy program activities. Partners should include state and local health departments, organizations other than epilepsy affiliates/chapters that promote or address epilepsy issues; organizations that improve health and quality of life for those with chronic disease, and organizations that address the health care and support needs of minority populations.

2. Develop multifaceted outreach activities to expand epilepsy awareness at national and local levels. Extend educational outreach to under served groups: Documentation should include listings of network activities from at least 15 grantee affiliates, an outline of the elements of the current national media campaign, types of educational and promotional materials developed and disseminated, communication channels developed or expanded, and target populations reached. Provide measurable outputs that demonstrate that the target populations have been reached.

3. Develop, disseminate and/or evaluate at least five types of targeted consumer and/or provider education materials that focus on epilepsy and seizures: Documentation should include type of materials (i.e., fact sheets, articles, brochures, exhibits, presentations, training modules, audio/video materials) target populations reached, and evaluation methods used.

Program Area 3: Prevention Activities

1. Develop health promotion/disease prevention web-based modules: Documentation should include a detailed description of module development, including scientific rationale, steps taken to develop module

based on the rationale, intended target audience, intended outcomes for participants, and proposed evaluation plans.

2. Provide information by documenting the response to phone calls, email requests, and other referred questions generated by the dissemination of web-based materials.

3. Develop partnerships with at least 30 diverse and active national organizations representing health care practitioners that will disseminate the web-based modules to their membership: Documentation should include communications methods developed or expanded to facilitate information exchange, demonstration of feedback from the national organizations, dissemination of materials, and signed documents of collaboration.

Program Area 4: Arthritis

1. Document and report the number of training programs offered and the number of people trained in Arthritis Foundation evidence-based programs (i.e., ASHC, PACE, AF Aquatics).

2. Develop no more than five innovative self management education or physical activity programs by providing detailed descriptions of the process and outcome of program development, including scientific rationale for the program, steps taken to develop program based on the rationale, intended target audience, intended outcomes for program participants, theoretical model or framework, results of pilot testing, and proposed evaluation plans.

3. Increase capacity to provide information by documenting an increased ability to handle phone and web requests and the development and production of new materials.

The following additional requirements are applicable to these programs. For a complete description of each, see Attachment II of the announcement.

- AR-7 Executive Order 12372 Review
- AR-8 Public Health System Reporting requirements
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the sections 301(a) and 317(k)(2) of the Public Health Service Act, (42 U.S.C. 241(a) and 247b(k)(2)), as amended. The

Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address <http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from: Michelle Copeland, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 02091, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2686, E-mail: stc8@cdc.gov.

See also the CDC home page on the Internet to obtain a copy of the announcement: <http://www.cdc.gov>.

For program technical assistance, contact: Mike Waller, Centers for Disease Control and Prevention, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway NE, Atlanta, GA, 30341-3717, Telephone: (770) 488-5264, E-mail: mnw1@cdc.gov.

Dated: May 6, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02-12087 Filed 5-14-02; 8:45 am]

BILLING CODE 4063-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0398]

Agency Information Collection Activities; Announcement of OMB Approval; Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information

Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 27, 2001 (66 FR 49388), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0340. The approval expires on April 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: May 8, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1034]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices; Device Tracking" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 8, 2002 (67 FR 5943), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the