

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants

Only states that received an AoA and CMS Aging and Disability Resource Center Grant in FY 2003 are eligible to apply. These states are Louisiana, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, Pennsylvania, Rhode Island, South Carolina, and West Virginia.

Only the state agency that was the ADRC applicant in FY 2003, or a state agency with a Memorandum of Agreement with the existing ADRC grantee (e.g. the Single State Agency on Aging, Single State Medicaid Agency or State Agency serving the target populations of people with disabilities) may apply for this Resource Center grant. The applicant agency must have the documented support, in the form of a Memorandum of Understanding and active participation by the Single State Agency on Aging, the Single State Medicaid Agency and the State Agency(s) serving the target population(s) of people with disabilities specified in the applicant's proposal.

A letter of support from the Governor indicating high-level state executive support and designating the lead agency is also required. Only one application per state will be accepted. "State" refers to the definition provided under 45 CFR 74.2. Executive Order 12372 is not applicable to these grant applications.

2. Cost Sharing or Matching

Grantees are required to make a non-financial or cash recipient contribution (match) of a minimum of five percent (5%) of the total grant award.

3. DUNS Number

All grant applicants must obtain a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number is free and easy to obtain from http://www.dnb.com/US/duns_update/.

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Application and Submission Information

1. Address To Request Application Package

Application materials can be obtained from <http://www.grants.gov> or <http://www.aoa.gov/doingbus/fundopp/fundopp.asp>.

Application materials are also available by writing to: U.S. Department of Health and Human Services, Administration on Aging, John Murphy, Center for Planning and Policy Development, Washington, DC 20201. Or by calling: 202-357-0136. Or e-mailing: john.murphy@aoa.hhs.gov.

2. Address for Application Submission

Electronic submissions must be sent to: <http://www.grants.gov>.

Applicants unable to submit their application via www.grants.gov may request permission to submit a hard copy from the AoA Project Officer: Greg Case: greg.case@aoa.hhs.gov. (202) 357-3442.

If you mail or hand delivers your application, you must submit one original application and two copies, plus a completed application checklist to AoA. The application deadline for applications sent by U.S. Postal Service must be post-marked by midnight July 21, 2006 or hand-delivered by 5 p.m. Eastern Time on July 21, 2006.

Submissions using the regular, U.S. Postal Service must be addressed to: Department of Health and Human Services, Administration on Aging, Grants Management Division, Washington, DC 20201. Attention: Stephen Daniels.

Submissions by courier, overnight delivery, delivered in person, etc. should be addressed to: Department of Health and Human Services, Administration on Aging, Grants Management Division, One Massachusetts Avenue, NW., Room 4604, Washington, DC 20001. Attention: Stephen Daniels.

3. Submission Dates and Times

To receive consideration, applications must be received by the deadline listed in the **DATES** section of this Notice.

V. Responsiveness Criteria

Each application submitted will be screened to determine whether it was received by the closing date and time.

Applications received by the closing date and time will be screened for completeness and conformity with the requirements outlined in Sections III and IV of this Notice and the Program Announcement. Only complete applications that meet these requirements will be reviewed and evaluated competitively.

VI. Application Review Information

Eligible applications in response to this announcement will be reviewed

according to the following evaluation criteria:

- Accomplishments and Problem Statement—Weight: 30 points
- Approach, Work Plan and Activities—Weight: 40 points
- Project Outcomes and Evaluation—Weight: 15 points
- Level of Effort (Organization and Management; Budget and Resources)—Weight: 15 points

VII. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration on Aging, Center for Planning and Policy Development, Attention: Greg Case, Washington, DC 20201. Telephone: (202) 357-3442.

Dated: May 22, 2006.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Head Start Program Grant Application and Budget Instrument.

OMB No.: 0970-0207.

Description: The Head Start Bureau is proposing to renew, without changes, the Head Start Grant Application and Budget Instrument, which standardizes the grant application information that is requested from all Head Start and Early Head Start grantees applying for continuation grants. The application and budget forms are available on a data diskette and on the Web at <http://www.acfgabi.com>. Completed applications can be transmitted electronically to Regional and Central Offices. The Administration on Children, Youth and Families believes that this application document makes the process of applying for Head Start program grants more efficient for applicants.

Respondents: Head Start and Early Head Start grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HS Grant and Budget Instrument	1,600	1	33	52,800

Estimated Total Annual Burden Hours: 52,800.

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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: May 18, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0211]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds

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 the collection of information contained in a guidance for industry entitled "Submitting and Reviewing Complete Responses to Clinical Holds." The guidance describes how to submit a complete response if an investigational new drug (IND) application is placed on clinical hold by FDA.

DATES: Submit written or electronic comments on the collection of information by July 24, 2006.

ADDRESSES: Submit electronic comments on the collection 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: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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: Submitting and Reviewing Complete Responses to Clinical Holds (OMB Control Number 0910-0445)—Extension

Section 117 of the Food and Drug Administration Modernization Act (Public Law 105-115), signed into law by the President on November 21, 1997, provides that a written request to FDA from the applicant of an investigation that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. A clinical hold is an order issued by FDA to the applicant to delay a proposed clinical investigation or to suspend an