

**FOR FURTHER INFORMATION CONTACT:** Mr. Thomas D. Vogelzonger, Public Health Advisor, Office of the Director, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE., Atlanta, GA 30341, Telephone 770.488.4823.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2003.

**Diane C. Allen,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-17562 Filed 7-10-03; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Development and Validation of Measures To Assess Outcomes of Mild Traumatic Brain Injury, Program Announcement 03106**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act

(Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Development and Validation of Measures To Assess Outcomes of Mild Traumatic Brain Injury, Program Announcement 03106.

*Times and Dates:* 6:30 p.m.-7 p.m., July 27, 2003 (Open). 7 p.m.-8 p.m., July 27, 2003 (Closed). 8:30 a.m.-5 p.m., July 28, 2003 (Closed).

*Place:* The Swissotel Atlanta Buckhead, 3391 Peachtree Road, NE., Atlanta, GA 30326, Telephone 404.365.0065.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 03106.

*For Further Information Contact:* Ms. Judy Stevens, Epidemiologist, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, Atlanta, GA 30341, Telephone 770.488.4649.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 7, 2003.

**Diane C. Allen,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03-17563 Filed 7-10-03; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Tribal Temporary Assistance for Needy Families (TANF) Quarterly Financial Report, ACF-196TT.

*OMB No.:* New Collection.

*Description:* The Tribal TANF Quarterly Financial Report provides specific data regarding expenditures and provides a mechanism for Tribes to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise the Administration for Children and Families' (ACF) ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. The following citation should be noted in regard to this collection: 45 CFR 286.255.

*Respondents:* Tribal TANF Agencies.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196TT .....	20	4	2	160

*Estimated Total Annual Burden Hours:* 160.

*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. E-mail address: [rsargis@acf.hhs.gov](mailto:rsargis@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: [lauren\\_wittenberg@omb.eop.gov](mailto:lauren_wittenberg@omb.eop.gov).

Dated: July 7, 2003.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 03-17529 Filed 7-10-03; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**[Program Announcement No. ACF/ACYF/HS-HSGS 2003-04]**

**Fiscal Year 2003 Discretionary Announcement for Head Start Graduate Student Research Grants; Availability of Funds and Request for Applications**

**AGENCY:** Administration for Children and Families (ACF) DHHS.

**ACTION:** Announcement of the availability of funds and request for doctoral level graduate student research projects (Priority Area 1.01) in partnership with Head Start programs,

and pre-doctoral level graduate student research partnership development projects (Priority Area 1.02) to develop ongoing research partnerships with Head Start programs.

**SUMMARY:** The Administration for Children and Families (ACF) Office of Planning, Research and Evaluation (OPRE) announces the availability of funds for Head Start Graduate Student Research Grants to support field-initiated research activities.

**CFDA #:** The Catalog of Federal Domestic Assistance number for all priority areas is 93.600

**DATES:** The closing time and date for receipt of applications is 5 p.m. (Eastern Time Zone) August 12, 2003. Regardless of the method by which they are delivered, applications must be received on or before the deadline date.

**Late Applications.** Applications that do not meet the criteria stated above, will be considered late applications. The Administration for Children and Families (ACF) will notify each late applicant that its application will not be considered in the current competition.

**Extension of Deadline.** ACF may extend an application deadline for applicants affected by acts of God (such as floods and hurricanes), when there is widespread disruption of mail service, or for other disruption of services that affect the public at large (such as prolonged electrical blackout). Authority to waive or extend deadline requirements rests with the Chief Grants Management Officer.

**Mailing and Delivery Instructions:** Applications may be sent through the U.S. Postal Service, delivered by private courier, or hand delivered to the ACF Operations Center at the address below. Applications delivered by hand must be received by the Operations Center during the normal working hours of 8 a.m. to 5 p.m., Monday through Friday and no later than 5 p.m. Eastern Time Zone on the deadline date. Applicants will receive a confirmation postcard upon receipt of applications. Head Start Research Support Team, 1749 Old Meadow Road, Suite 600, McLean, VA 22102.

All packages should be clearly labeled as follows: Application for Head Start Graduate Student Research Grants: Priority Area (indicate 1.01 or 1.02).

**FOR FURTHER INFORMATION CONTACT:** The Head Start Research Support Technical Assistance Team (1-877) 663-0250, is available to answer questions regarding application requirements and to refer you to the appropriate contact person in ACF for programmatic questions. You may e-mail your questions to: [hsr@xtria.com](mailto:hsr@xtria.com).

Grants Management Contact: William Wilson, Grants Management Officer, Room 2220 Switzer Building, 330 C Street SW., Washington, DC 20447. Telephone Number (202) 205-8913 or e-mail [WWilson@acf.hhs.gov](mailto:WWilson@acf.hhs.gov).

In order to determine the number of expert reviewers that will be necessary, if you are going to submit an application, *you must send a post card, call or e-mail at least two weeks prior to the submission deadline date with the following information: the name, address, telephone and fax number, e-mail address of the principal investigator, and the name of the university or non-profit institution to: Head Start Research Support Team, 1749 Old Meadow Road, Suite 600, McLean, VA 22102, (1-877) 663-0250, E-mail [hsr@xtria.com](mailto:hsr@xtria.com).*

**SUPPLEMENTARY INFORMATION:** The Supplementary Information section consists of four parts. Part I provides general information about the Head Start research activities, authorities, funding priorities, and the application process. Part II describes the Head Start Graduate Student Research Grants (Priority Area 1.01). Part III describes the Head Start Graduate Student Partnership Development Grants (Priority Area 1.02). Part IV includes two appendices that include all requirements for applications. Appendix 1 provides detailed instructions for preparing and submitting applications. Appendix 2 contains the OMB-approved Uniform Project Description.

## Part I. General Information

### A. Purpose of Announcement

The purpose of this announcement is to announce the availability of funds for Head Start Graduate Student Research Grants to support field-initiated research activities in partnership with Head Start programs and to develop ongoing research partnerships with Head Start programs.

### B. Background

Priority Area 1.01 and 1.02: Head Start Graduate Student Research Grants and Research Partnership Development Grants

Since 1991, ACF has explicitly supported the relationship between established Head Start researchers and their graduate students by awarding research grants, on behalf of specific graduate students, to conduct research in Head Start communities. As many previously funded Head Start graduate students have continued to make significant contributions to the early

childhood research field as they have pursued their careers, this funding mechanism is an important research capacity-building effort. To ensure that future research is responsive to the changing needs of low-income families, graduate students need strong and positive role models. Therefore, Head Start's support of the partnership between students and their mentors is essential. The unique partnership that is forged between mentor and student, within the Head Start research context, serves as a model for the establishment of other partnerships within the community (e.g., researcher-Head Start staff, researcher-family, etc.). This foundation helps foster the skills necessary to build a graduate student's trajectory of successful partnership-building and contributions to the scientific community. Within this nurturing and supportive relationship, young researchers are empowered to become autonomous researchers, learning theory, as well as the process of interacting with the various members and relevant organizations within their communities.

ACF further recognizes that effectively developing new research partnerships between researchers and Head Start communities requires considerable planning, effort, and commitment. In order to encourage the development of such new research partnerships, and to facilitate the entry of new mentor/student teams to the field of Head Start research, it is also essential to support the process of partnership development and research conceptualization. Therefore, a new priority area has been added this year for that purpose.

Thus, the goals of the two priority areas within the Head Start Graduate Student Research Grant program can be summarized as follows:

1. Provide direct support for graduate students as a way of encouraging the conduct of research with Head Start populations, thus contributing to the knowledge base about the best approaches for delivering services to diverse, low-income families and their children;
2. Promote mentor-student relationships which support students' graduate training and professional development as young researchers engaged in policy-relevant, applied research;

3. Emphasize the importance of developing true working research partnerships with Head Start programs and other relevant entities within the community, thereby fostering skills necessary to build a student's trajectory of successful partnership-building and

contributions to the scientific community; and

4. Support the active communication, networking and collaboration among graduate students, their mentors and other prominent researchers in the field, both during their graduate training, as well as into the early stages of their research careers.

While the specific topics addressed under these Graduate Student Research Grants are intended to be field-initiated, applicants who address issues of both local and national significance will be most likely to succeed. Some illustrative examples of such topics include, but are not limited to the areas of school readiness, children's mental health, serving an increasingly culturally and linguistically diverse population of children and families and promoting child well-being by strengthening responsible fatherhood and healthy marriages in Head Start families.

#### C. Statutory Authority and Other Citations

*Statutory authority:* Section 649 of the Head Start Act, as amended by the Coats Human Services Reauthorization Act of 1998 (Pub. L. 105–285) and 42 U.S.C. 9844.

*Paperwork Reduction Act of 1995 (Pub. L. 104–13):* Public reporting for this collection of information is estimated to average 40 hours per response, including time for reviewing instructions, gathering and maintaining data needed and reviewing the collection of information.

The project description is approved under OMB control Number 0970–0139 which expires 12/31/03.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

#### D. Priority Areas, Number of Awards, Project Duration, and Funding Levels

In Fiscal Year 2003, ACF anticipates funding between 5 and 10 new projects in Priority Area 1.01 and between 2 and 8 new projects in Priority Area 1.02, pending availability of funds and receipt of satisfactory applications. ACF intends to commit up to \$200,000 per year to fund new grants in response to both priority areas within this announcement. It is unlikely that any individual mentor will be funded for more than one graduate student research grant if there are at least 10 applications from different mentors/institutions that qualify for support.

Any application that exceeds the maximum dollar range will be considered “non-responsive” and

subsequently returned to the applicant without further review.

*Matching Requirement:* There is no matching requirement.

*Priority Area 1.01. Head Start Graduate Student Research Grants:* The maximum Federal share will range between \$10,000–\$20,000 for the first 12-month budget period or a maximum of \$40,000 for a 2-year project period.

For Priority Area 1.01, requests for a second year of funding within the project period should be identified in the current application (on SF-424A), but such requests will be considered at a later date on a noncompetitive basis, subject to the graduate student's eligibility status, the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.

*Priority Area 1.02. Head Start Graduate Student Partnership Grants:* The maximum Federal share will range between \$2,500–\$5,000 for the 12-month budget period.

#### E. Application Process

This announcement includes all of the information needed to apply for funding in each of the priority areas. Detailed instructions for preparing and submitting applications are contained in the appendices. Applicants are cautioned to follow the prescribed content and format in preparing their application packages. Each priority area describes the purpose, goals, technical requirements and evaluation criteria against which proposals will be reviewed. The Standard Federal Forms that must be included in applications can be downloaded from the Internet at <http://www.acf.hhs.gov/programs/ofs/>.

#### F. Proposal Review, Selection and Award

1. Each application will be screened to determine whether the applicant organization is eligible as specified in each of the priority areas. Applications from ineligible organizations will be excluded from the review.

1. The review will be conducted in Washington, DC. Expert reviewers will include researchers, Federal or State staff, and other individuals experienced in Head Start or related research and evaluation. A panel of at least three reviewers will evaluate each application to determine the strengths and weaknesses of the proposal in terms of the Head Start's research goals and expectations, requirements for the Project Narrative Statement, and evaluation criteria for the priority area under consideration.

3. Given the involvement of non-Federal reviewers, applicants have the option of omitting from the application copies (but not the original), specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. If the applicant omits individual salary information on application copies, the copies must include summary salary information.

4. Panelists will provide written comments and assign numerical scores for each application. The indicated point value for each criterion is the maximum numerical score for that criterion. The assigned scores for each criterion will be summed to yield a total evaluation score for the proposal.

5. In addition to the panel review, ACF may solicit comments from other Federal offices and agencies, States, non-governmental organizations, and individuals whose particular expertise is identified as necessary for the consideration of technical issues arising during the review. ACF will consider their comments, along with those of the panelists, when making funding decisions. ACF will also take into account the best combination of proposed projects to meet overall research goals.

6. The Director of the Office of Planning, Research and Evaluation in the Administration for Children and Families (ACF) will make the final selection of the applicants to be funded. Applications may be funded in whole or in part depending on: (1) The rank order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects which best meets the Bureau's research objectives; (4) the funds available; and (5) other relevant considerations.

7. Selected applicants will be notified through the issuance of a Financial Assistance Award. That document establishes the funding level, terms and conditions of the award, reporting requirements, effective date of the award, budget period for which support is given, and total project period for which support is provided.

8. Grants to successful applications will be awarded by September 30, 2003.

#### G. Type and Frequency of Post-Award Reporting Requirements

All grantees will be required to submit semi-annual progress and fiscal reports as well as a final report.

#### Part II: Priority Area 1.01 Head Start Graduate Student Research Grants

*Eligible Applicants:* Institutions of higher education on behalf of *doctoral-*

*level graduate students.* Doctoral students must have completed their Master's Degree or equivalent in the field of doctoral study and submitted formal notification to ACF by *August 15, 2003.*

To be eligible to administer the grant on behalf of the student, the institution must be fully accredited by one of the regional accrediting commissions recognized by the Department of Education and the Council on Post-Secondary Accreditation. Faith-based institutions are also eligible to apply. Although the faculty mentor is listed as the Principal Investigator, this grant is intended for dissertation research for an individual student. Information about both the graduate student and the student's faculty mentor is required as part of this application. Any resultant grant award is not transferable to another student. The award may not be divided between two or more students.

Private, non-profit institutions are encouraged to submit with their applications the optionally survey located under "Grant Manuals & Forms" at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

*Additional Requirements:*

- A university faculty member must serve as a mentor to the graduate student; this faculty member is listed as the "Principal Investigator." The application must include a letter from this faculty member stating that s/he has reviewed and approved the application, the status of the project as *dissertation research*, the student's status in the doctoral program, and a description of how the faculty member will regularly monitor the student's work.

- The research project must be an independent study conducted by the individual graduate student or well-defined portion(s) of a larger study currently being conducted by a faculty member. If the project is part of a larger research effort, the proposal must clearly distinguish between the student's portion of the research activities and those of the larger project. The graduate student must have primary responsibility for the proposed study described in the application.

- The graduate student must enter into a partnership with a Head Start or Early Head Start program for the purposes of conducting the research.

- The application must contain (A) a letter from the Head Start or Early Head Start program certifying that they have entered into a research partnership with the applicant (graduate student) and (B) a separate letter certifying that the application has been reviewed and approved by the Head Start Program Policy Council. Notification of approval

or pending approval by the Policy Council must be received from the official representative of the Policy Council and not an individual from the Head Start or Early Head Start program itself.

- The graduate student applicant must agree to attend *two* meetings each year of the grant. The first meeting consists of the annual meeting for all Head Start Graduate Students. This annual grantee meeting is typically scheduled during the summer or fall of each year and is held in Washington, DC. The fall 2003 meeting will be held on Oct. 20–21, 2003. During this meeting, each student typically presents a brief overview of his or her study (*e.g.*, the study design, participants, measures, and/or findings, as they become available). The intended goal of the meeting is to stimulate potentially useful and constructive feedback from other students and mentors, as well as to facilitate collaboration, networking and mentoring activities.

The second meeting each year alternates between the biennial Head Start National Research Conference in Washington, DC (June 28 to July 1, 2004) and the biennial meeting of the Society for Research in Child Development-SRCD (April, 2005). At a minimum, students usually are provided the opportunity to present information on their respective studies in a poster session format, although both meetings also provide other networking and mentoring activities. The grant budget should reflect travel and housing funds for the graduate student for all four of these meetings (or two if only applying for only one year of funding).

- Given the strong emphasis that is placed on supporting the mentor-student relationship, the faculty mentors are strongly encouraged to attend and participate in the activities of the annual grantee meeting for all Head Start Graduate Students. The budget should reflect travel funds for such purposes, as appropriate. However, if the faculty mentor does plan to attend the annual Graduate Student grantee meeting, but will utilize another source of travel funds, such arrangements are encouraged and should be noted in the application.

- Due to the small amount of the grant, the applicant's institution is strongly encouraged to waive indirect costs.

- Contact information, including phone numbers, addresses and e-mail addresses, for *both* the graduate student applicant and faculty mentor must be included in the application.

- The graduate student must write the application in its entirety, consistent

with the format and style guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001) and the general principles and guidelines of the *Ethical Principles of Psychologists and Code of Conduct 2002* (APA, 2002).

*Project Duration:* The announcement for priority area 1.01 is soliciting applications for project periods up to two years. Grant awards, on a competitive basis, will be for a one- to two-year project period, the budget will be funded in one-year increments. It should be noted, that if the graduate student, on whose behalf the University is applying, expects to receive his/her degree by the end of the first one-year budget period, the applicant should request a one-year project period only. A second year budget-period will not be granted if the student has graduated by the end of the first year. Applications for continuation grants funded under these awards beyond the initial one-year budget period, but within the two-year project period, will be entertained in the subsequent year on a non-competitive basis, subject to availability of funds, satisfactory progress of the grantee and a determination that continued funding would be in the best interest of the Government.

Criteria for Priority Area 1.01—Head Start Graduate Student Research Grants—The three criteria that follow will be used to review and evaluate each application under this priority area (presented here in descending order of numerical weighting—see instructions in Appendix 2). Address each in the Project Narrative Section of the application. The point values indicate the maximum numerical weight each criterion will be accorded in the review process. (100 points total).

1. Approach 40 points

- The extent to which there is a discrete project designed by the graduate student. If the proposed project is part of a larger study designed by others, the approach section should clearly delineate the research component to be carried out by the student and how it is distinguished from the larger research project.

- The extent to which the research design is appropriate and sufficient for addressing the questions of the study.

- The extent to which the planned research specifies the measures to be used, their psychometric properties, and contains an adequately detailed description of the proposed analyses to be conducted.

- The extent to which the planned measures have been shown to be appropriate and sufficient for the

questions of the study, and the population to be studied.

- The extent to which the planned measures and analyses are consistent with one another, and reflect knowledge and use of state-of-the-art measures and analytic techniques, or advance the state-of-the-art, as appropriate.

- The extent to which the analytic techniques are appropriate for the specific research question(s) under consideration.

- The extent to which the proposed sample size is sufficient to answer the range of proposed research questions for the study.

- The extent to which the scope of the project is reasonable for the funds available and feasible for the time frame specified.

- The extent to which the planned approach reflects sufficient written input from and partnership with the Head Start program (including the separate required review and written approval from the Head Start program and the Head Start Program Policy Council).

- The extent to which the budget and budget justification are appropriate for carrying out the proposed project.

## 2. Staff and Position Data 35 points

- The extent to which the faculty mentor and graduate student possess the research expertise necessary to conduct the study as demonstrated in the application and information contained in their vitae.

- The principal investigator/faculty mentor has earned a doctorate or equivalent in the relevant field and has first or second author publications in major research journals.

- The extent to which the faculty mentor and graduate student reflect an understanding of and sensitivity to the issues of working in a community setting and in partnership with Head Start program staff and parents.

- The adequacy of the time devoted to this project by the faculty mentor for mentoring the graduate student. The proposal should include evidence of the faculty mentor's commitment to mentoring the individual graduate student, and as appropriate, willingness to serve as a resource to the broader group of Head Start Graduate Students funded under this award.

## 3. Results or Benefits Expected 25 points

- The research questions are clearly stated.

- The presentation reflects original work done by the student (consistent with the general principles and guidelines of the *Ethical Principles of*

*Psychologists and Code of Conduct 2002* (APA 2002).

- The extent to which the questions are of importance and relevance for low-income children's development and welfare.

- The extent to which the research study makes a significant contribution to the knowledge base.

- The extent to which the literature review is current and comprehensive and supports the need for the study.

- The extent to which the literature review has a complete set of reference citations and is written consistent with the guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001).

- The extent to which the questions that will be addressed or the hypotheses that will be tested are sufficient for meeting the stated objectives.

- The extent to which the proposed project is appropriate to the student's level of ability and the stated time frame for completing the project.

### Part III: Priority Area 1.02 Head Start Graduate Student Research Partnership Development Grants

*Eligible Applicants:* Institutions of higher education on behalf of *graduate students enrolled in a doctoral program.*

To be eligible to administer the grant on behalf of the student, the institution must be fully accredited by one of the regional accrediting commissions recognized by the Department of Education and the Council on Post-Secondary Accreditation. Faith-based institutions are also eligible to apply. Although the faculty mentor is listed as the Principal Investigator and must be committed to taking a central role in maintaining an ongoing research partnership with a Head Start program, this grant is intended for an individual student to be the primary conduit through which the research-related relationship is forged. Information about both the graduate student and the student's faculty mentor is required as part of this application. Any resultant grant award is not transferable to another student. The award may not be divided between two or more students.

#### Additional Requirements

- A university faculty member must serve as a mentor to the graduate student; this faculty member is listed as the "Principal Investigator." The application must include a letter from this faculty member stating that s/he has reviewed and approved the application and describing, in as much detail as is possible, the potential for the research partnership development project to lead to a research effort that would include

the student's dissertation study. It should also include a statement of the student's status in the graduate program and a description of how the faculty member will regularly monitor the student's work.

- The research partnership development project must be conducted by the individual graduate student or be a well-defined portion(s) of a larger research effort currently being conducted by a faculty member. If the project is part of a larger research partnership-building effort, the proposal must clearly distinguish between the student's portion and the activities of the larger research project. The graduate student must have primary responsibility for the proposed research efforts described in the application.

- The graduate student must begin to forge a research partnership with a Head Start or Early Head Start program. While one of the long-term purposes of the relationship should be to generate a doctoral dissertation research opportunity in the Head Start setting, the student should take an approach that is based in community/ecological/empowerment models, in which research needs are considered in the larger context of program needs, as well as mutually beneficial and empowering relationships. Appropriate activities during the grant period may include, but are not limited to, providing direct services and assistance to Head Start or Early Head Start programs with program activities, conducting assets/needs assessments, conducting focus groups, jointly identifying or defining problems with Head Start partners, training staff and other activities that foster collaborative, reciprocal relationships with Head Start partners.

- Graduate students will be expected to identify (a) a set of goals and objectives for the year, as well as a set of benchmarks for guiding and assessing incremental progress toward attaining these goals and objectives, and (b) specific *products* they expect to generate during the grant period such as community assets/needs assessments, problem descriptions, summaries of focus group findings or training efforts, and/or drafts of dissertation proposals.

- Grant recipients are encouraged to build upon their work by subsequently applying for the Head Start Graduate Student Research Grants (Priority 1.01) to support doctoral dissertation research.

- The application must contain (A) a letter from at least one Head Start or Early Head Start program certifying that they are receptive to exploring a potential research partnership with the applicant and (B) a separate letter

certifying that the proposed partnership project has been reviewed and approved by the Head Start Program Policy Council. Notification of approval or pending approval by the Policy Council must be received from the official representative of the Policy Council and not an individual from the Head Start or Early Head Start program itself.

- The graduate student applicant must agree to attend the annual meeting for all Head Start Graduate Student Research grantees. This annual grantee meeting is typically scheduled during the summer or fall of each year and is held in Washington, DC. The fall 2003 meeting will be held Oct. 20–21, 2003. During this meeting, each student typically presents a brief overview of his or her study or proposed project. The intended goal of the meeting is to stimulate potentially useful and constructive feedback from other students and mentors, as well as to facilitate collaboration, networking and mentoring activities. The grant budget should reflect travel and housing funds for the graduate student for this meeting.

- Due to the small amount of the grant, the applicant's institution is strongly encouraged to waive indirect costs.

- Contact information, including phone numbers, addresses and e-mail addresses, for *both* the graduate student applicant and faculty mentor must be included in the application.

- The graduate student must write the application, consistent with the format and style guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001) and the principles and guidelines from the *Ethical Principles of Psychologists and Code of Conduct (APA 2002)*.

*Project Duration:* The announcement for priority area 1.02 is soliciting applications for project periods up to *one year*.

**CRITERIA for Priority Area 1.02—Head Start Graduate Student Research Partnership Development Grants—**The three criteria that follow will be used to review and evaluate each application under this priority area. Address each in the Project Narrative Section of the application (presented here in descending order of numerical weighting—see instructions in Appendix 2). The point values indicate the maximum numerical weight each criterion will be accorded in the review process. (100 points total).

#### 1. Approach 40 points

- The extent to which there is a discrete project designed by the graduate student. If the proposed project

is part of a larger project designed by others, the approach section should clearly delineate the research partnership development component to be carried out by the student and how it is distinguished from the larger project.

- The extent to which the goals and objectives of the proposed activities, as well as the set of benchmarks for guiding and assessing progress, are clearly articulated and reflect an appropriate understanding of how these activities will fit within the context and complexities of the Head Start program's operations.

- The scope of the project is reasonable for the funds available and feasible for the time frame specified.

- The extent to which the planned approach or proposed research partnership activities reflect sufficient opportunities for written input from and an active partnership with the Head Start program (including the separate required review and written approval of the proposed partnership activities from the Head Start program and the Head Start Program Policy Council).

- The extent to which the budget and budget justification are appropriate for carrying out the proposed research project development activities.

- The extent to which proposed products reflect concrete and measurable steps toward design of a future dissertation project.

#### 2. Staff and Position Data 35 points

- The extent to which the faculty mentor and graduate student possess the expertise necessary to successfully form a research partnership with a Head Start program as demonstrated in the application and information contained in their vitae.

- The principal investigator/faculty mentor has earned a doctorate or equivalent in the relevant field and has first or second author publications in major research journals.

- The extent to which the faculty mentor and graduate student reflect an understanding of and sensitivity to the issues of working in a community setting and in a reciprocal partnership with Head Start program staff and parents.

- The adequacy of the time devoted to this project by the faculty mentor for mentoring the graduate student. The proposal should include evidence of the faculty mentor's commitment to mentoring the individual graduate student, and as appropriate, willingness to serve as a resource to the broader group of Head Start Graduate Students funded under this award.

- The extent to which the mentor-mentee relationship is clearly described and has the potential to continue throughout the student's dissertation process.

#### 3. Results or Benefits Expected 25 points

- The presentation reflects original work done by the student (consistent with the general principles and guidelines of the *Ethical Principles of Psychologists and Code of Conduct 2002* (APA 2002)).

- The extent to which the literature review, as well as a description of the needs of the local community if appropriate, is current and comprehensive and supports the need for developing this or similar research partnerships.

- The extent to which proposed goals and objectives for the year address the needs identified.

- The extent to which the specific *products* to be generated through the grant, as well as the benchmarks for assessing progress toward these goals and objectives, are clearly described and will potentially benefit the Head Start and/or research communities.

- The extent to which the literature review has a complete set of reference citations and is written consistent with the guidelines of the *Publication Manual of the American Psychological Association, 5th ed.* (APA 2001).

- The extent to which the proposed project is appropriate to the student's level of ability and the stated time frame for completing the project.

- The extent to which potential research questions are clearly stated and are of importance and relevance for low-income children's development and welfare.

### Part IV. Appendices

#### Appendix 1: Contents and Format of the Application

Clarity and conciseness are of utmost importance. ACF strongly encourages applicants to limit their applications to 100 pages, double-spaced and single-sided, with standard one-inch margins and 12 point fonts. This includes the entire Project Narrative Statement including text, tables, charts, graphs, resumes, corporate statements and appendices.

Applicants are cautioned to include all required forms and materials, organized according to the required format. The application packet must include the following items in order:

1. A cover letter that includes the announcement number, priority area and contact information.

2. Standard Federal Forms  
 a. Standard Form 424, "Application for Federal Assistance." This form must be completed, signed, and included with the application.

b. Standard Form 424A, "Budget Information—Non-Construction Programs." This form must be completed and included with the application.

c. Standard Form 424B, "Assurances: Non-Construction Programs." This form must be completed, signed, and included with the application.

d. Assurance/Identification/Certification/Declaration Regarding Protection of Human Subjects. This form must be completed, signed, and included with the application.

e. Certifications Regarding Lobbying. Applicants must provide a certification regarding lobbying when applying for an award in excess of \$100,000.

Applicants must sign and return the certification with their applications.

f. Standard Form LLL, "Disclosure of Lobbying Activities." Applicants must disclose lobbying activities when applying for an award in excess of \$100,000. Applicants who have used non-Federal funds for lobbying activities in connection with receiving assistance under this announcement shall complete a disclosure form to report lobbying. Applicants must sign and return the disclosure form, if applicable, with their applications.

g. Certification Regarding Drug-Free Workplace Requirements. Applicants must make the appropriate certification of their compliance with the Drug-Free Workplace Act of 1988. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

h. Certification Regarding Debarment, Suspension, and Other Responsibility Matters. Applicants must make the appropriate certification that they are not presently debarred, suspended, or otherwise ineligible for an award. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

i. Certification Regarding Environmental Tobacco Smoke. Applicants must make the appropriate certification of their compliance. By signing and submitting the application, the applicant is providing the certification and need not mail back the certification with the application.

3. For-profit entities wishing to receive a grant directly must provide a letter indicating their willingness to waive their profit. Non-profit organizations must submit proof of non-

profit status in the application at the time of submission. The applicant can demonstrate proof of non-profit status in any one of five ways, by providing:

a. A copy of the organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)3 of the IRS code;

b. A copy of the currently valid IRS tax exemption certificate;

c. A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals;

d. A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

e. Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

Private, non-profit institutions are encouraged to submit with their applications the optional survey located under "Grant Manuals & Forms" at <http://www.acf.hhs.gov/programs/ofsf/forms.htm>.

4. Administrative requirements: 45 CFR Parts 74 and 92.

5. Executive Order 12372—Single Point of Contact  
 This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs", and 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Program and Activities". Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, and Wyoming have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-six jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as

possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodation or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, ACYF's Office of Grants Management, Room 2220 Switzer Building, 330 C Street SW., Washington, DC 20447, Attn: Head Start Discretionary Research Grants Announcement. A list of the Single Points of Contact (SPOCs) for each State and Territory can be found on the following web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

5. Table of Contents  
 6. Project Abstract (not to exceed one page) for use in official briefings, decision packages, and public announcement of awards.

7. Project Narrative Statement (See instructions in Appendix 2 and Evaluation Criteria for each Priority described in this announcement.)

8. *Appendices*: All supporting materials and documents should be organized into appropriate appendices and securely bound to the application package. Applicants are reminded that the total page limitation applies to both narrative text and supporting materials.

a. Contact Information for all Key Staff  
 b. Resumes  
 c. Letters of Support, if appropriate  
 d. Other

9. *Number of Copies and Binding*: An original and two copies of the complete application packet must be submitted. Each copy of the application should be securely stapled in the upper left-hand corner, clipped, or secured at the top with a two-hole punch fastener. Because each application will be duplicated for the review panel, do not use non-

removable binders. Do not include tabs, plastic inserts, brochures, videos, or any other items that cannot be photocopied.

## **Appendix 2: Uniform Project Description**

### **Part 1 The Project Description Overview**

#### *Purpose*

The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, all information requested through each specific evaluation criteria should be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application.

#### *General Instructions*

ACF is particularly interested in specific factual information and statements of measurable goals in quantitative terms. Project descriptions are evaluated on the basis of substance, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant-funded activity should be placed in an appendix.

Pages should be numbered and a table of contents should be included for easy reference.

### **Part 2 General Instructions for Preparing a Full Project Description**

#### *Introduction*

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions and the specified evaluation criteria. The instructions give a broad overview of what your project description should include while the evaluation criteria expands and clarifies more program-specific information that is needed.

#### *Project Summary/Abstract*

Provide a summary of the project description (a page or less) with reference to the funding request.

#### *Objectives and Need for Assistance*

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

#### *Approach*

Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

#### *Evaluation*

Provide a narrative addressing how the results of the project and the

conduct of the project will be evaluated. In addressing the evaluation of results, state how you will determine the extent to which the project has achieved its stated objectives and the extent to which the accomplishment of objectives can be attributed to the project. Discuss the criteria to be used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the project results and benefits are being achieved. With respect to the conduct of the project, define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

#### *Additional Information*

Following are requests for additional information that need to be included in the application:

#### *Staff and Position Data*

Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

#### *Organizational Profiles*

Provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission.

The non-profit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code, or by providing a copy of the currently valid IRS tax exemption certificate, or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

#### *Letters of Support*

Provide statements from community, public and commercial leaders that

support the project proposed for funding. All submissions should be included in the application OR by application deadline.

#### *Budget and Budget Justification*

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF-424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

#### *General*

The following guidelines are for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, "Federal resources" refers only to the ACF grant for which you are applying. Non-Federal resources are all other resources. It is suggested that budget amounts and computations be presented in a columnar format: first column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

#### *Personnel*

*Description:* Costs of employee salaries and wages.

*Justification:* Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

#### *Fringe Benefits*

*Description:* Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

*Justification:* Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

#### *Travel*

*Description:* Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel).

*Justification:* For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops should be detailed in the budget.

#### *Equipment*

*Description:* "Equipment" means an article of non-expendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (Note: Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

*Justification:* For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

#### *Supplies*

*Description:* Costs of all tangible personal property other than that included under the Equipment category.

*Justification:* Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

#### *Contractual*

*Description:* Costs of all contracts for services and goods except for those which belong under other categories such as equipment, supplies, construction, etc. Third-party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed

by the applicant, should be included under this category.

*Justification:* All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use 45 CFR Parts 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at 100,000). Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

**Note:** Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

#### *Other*

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

*Justification:* Provide computations, a narrative description and a justification for each cost under this category.

#### *Indirect Charges*

*Description:* Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

*Justification:* An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested,

those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

#### *Nonfederal Resources*

*Description:* Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF-424.

*Justification:* The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

Dated: July 8, 2003.

#### **Howard Rolston,**

*Director, Office of Planning, Research, and Evaluation, Administration for Children and Families.*

[FR Doc. 03-17605 Filed 7-10-03; 8:45 am]

BILLING CODE 4184-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 2003N-0017]

#### **Agency Information Collection Activities; Submission for OMB Review; Comment Request; Impact of Risk Management Programs on the Practice of Pharmacy**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 August 11, 2003.

**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.

#### **Impact of Risk Management Programs on the Practice of Pharmacy**

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the survey entitled "Impact of Risk Management Programs on the Practice of Pharmacy."

Risk management (RM) programs are reviewed by divisions in the Center for Drug Evaluation and Research (CDER) as part of the new drug application (NDA) review process as well as during the postmarketing period. In an effort to address safety risks associated with drug therapy, several RM programs have been implemented (for example, for clozapine, thalidomide, and bosentan). Many RM programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures. Currently, the impact of RM programs on the practice of pharmacy in terms of pharmacists' compliance, knowledge, burden, and barriers is not known.

The survey is a small investigator-initiated research project to improve science safety review within CDER. The research is intended to help FDA safety evaluators of drug adverse events understand the larger context of RM programs and how they are perceived and implemented by pharmacists. The study is independent from the Prescription Drug User Fee Act III guidance that is currently under development on RM.

The descriptive survey will be sent to a representative sampling of pharmacists in the United States. Approximately 5,000 pharmacists will be chosen at random from listings of licensed pharmacists obtained from participating U.S. State Boards of Pharmacy. Because the number of licensed pharmacists in each State varies and the number of respondents from each State cannot be predicted, either a simple random or a stratified sample design will be used, depending on whether there is a sufficient number of participating pharmacists to evaluate regional differences. The geographic regions will be classified by location in one of the four geographic regions of the United States corresponding to those used by the U.S. Bureau of Census (northeast, midwest, south, and west).

The survey will be conducted via first-class mail. The survey will be mailed with a cover letter to randomly chosen pharmacists along with a preaddressed, stamped return envelope. To ensure anonymity and confidentiality, no premarkings or numbering systems will be recorded on the survey or return envelope.

From the sample size of approximately 5,000 pharmacists, the desirable response rate is approximately 75 to 85 percent. If needed, actions will be taken to increase the response rate, such as resending the survey approximately 2 weeks after the initial mailing.

In the **Federal Register** of February 12, 2003 (68 FR 7124), FDA published a notice requesting comments on FDA's burden estimates to conduct a descriptive survey of pharmacists to evaluate pharmacists' knowledge of RM programs, identify barriers to compliance, and assess the impact of these programs on the practice of pharmacy. FDA received one comment. A summary of the comment and FDA's responses are in the following paragraphs.

Concerning the issue of sampling methodology, the comment said that the primary focus of the survey should be on community pharmacists who are most likely to dispense medications associated with RM programs.

FDA believes that RM programs may affect pharmacists in all practice settings; during drug dispensing, answering drug information questions, and/or monitoring drug therapy. For this reason, the primary focus of the survey is not on community pharmacists. However, FDA will analyze responses according to pharmacy practice settings (for example, retail, hospital, and long-term care).

The comment said that the sampling frame should be stratified to obtain an equal distribution of pharmacists working in chain versus independent pharmacies.

FDA notes that the primary objective of the survey is not to compare the responses between chain and independent pharmacies. In addition, because the sampling frame does not include the setting information in which the pharmacist works, the agency cannot stratify the sampling frame. However, the survey contains a question regarding the practice setting of surveyed pharmacists and FDA intends to analyze this data.

The comment said that the survey should be accompanied by an explanation or incentive that provides a compelling reason for a pharmacist to complete it.