

the appropriate and only qualified organization to address the activities described under this program announcement.

ATPM is the only association that has an established membership of diverse professionals that includes teachers, practitioners, administrators, and residents in the specialty of preventive medicine, and graduate students from schools of medicine and public health, as well as from public health agencies. For 62 years, ATPM and its members have been in the forefront of advancing, promoting, and supporting health promotion and disease prevention in the education of physicians and other health professionals. ATPM provides an essential connection to individuals and institutions devoted to health promotion and disease prevention education.

### C. Funding

Approximately \$15,000,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before September 1, 2005 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

### D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact:

Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, telephone: 770-488-2700.

For technical questions about this program, contact: John (Jack) Rogers, Technical Review Administrator, The Coordinating Center for Health Information and Services (CoCHIS), 4770 Buford Hwy, Mailstop K-38, Atlanta, GA 30341, telephone: 770-488-2516, e-mail: [JJRogers@cdc.gov](mailto:JJRogers@cdc.gov).

Dated: February 2, 2005.

#### William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.  
[FR Doc. 05-2372 Filed 2-7-05; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Center for Environmental Health/Agency for Toxic Substances and Disease Registry; The Community and Tribal Subcommittee of the Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH)/Agency for Toxic Substances and Disease Registry (ATSDR): Teleconference

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention, NCEH/ATSDR announces the following subcommittee meeting:

*Name:* Community and Tribal Subcommittee (CTS).

*Time and Date:* 3 p.m.-4:30 p.m., February 28, 2005.

*Place:* The teleconference will originate at the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

*Status:* Open to the public, teleconference access limited only by availability of telephone ports.

*Purpose:* Under the charge of the Board of Scientific Counselors, NCEH/ATSDR the Community and Tribal Subcommittee will provide the BSC, NCEH/ATSDR with a forum for community and tribal first-hand perspectives on the interactions and impacts of the NCEH/ATSDR's national and regional policies, practices and programs.

*Matters to be Discussed:* The teleconference agenda will include discussions on obtaining directions from the BSC on their expectations from the CTS; the community tool kit; faith-based initiative/emergency preparedness; partnering with the Program Review Committee; and an open discussion for other important issues.

Agenda items are subject to change as priorities dictate.

*Supplementary Information:* This conference call is scheduled to begin at 3 p.m. eastern standard time. To participate in the teleconference, please dial (877) 315-6535 and enter conference code 383520.

*For Further Information Contact:* Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, M/S E-28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/498-0003.

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: February 1, 2005.

Alvin Hall,

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

[FR Doc. 05-2376 Filed 2-7-05; 8:45 am]

BILLING CODE 4163-70-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Notice of Issuance of Final Policy Directive

**AGENCY:** Administration for Native Americans (ANA), HHS.

**SUMMARY:** The Administration for Native Americans (ANA) herein describes its issuance of final interpretive rules, general statements of policy and rules of agency procedure or practice relating to the Social and Economic Development Strategies (SEDS), Language Preservation and Maintenance (hereinafter referred to as Native Language), and Environmental Regulatory Enhancement (hereinafter referred to as Environmental) programs.

**DATES:** January 28, 2005.

**FOR FURTHER INFORMATION CONTACT:** Sheila Cooper, Director of Program Operations at (877) 922-9262.

#### **SUPPLEMENTARY INFORMATION:**

##### *Background*

Pursuant to section 814 of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b-1, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules, statements of general policy, and rules of agency procedure or practice, and to give notice of the final adoption of such changes at least 30 days before the changes become effective.

The Administration for Native Americans (ANA) published a Notice of Public Comment (NOPC) in the **Federal Register** on December 27, 2004 (69 FR 77251), on the proposed ANA policy and program clarifications, modifications, and activities for the FY 2005 Program Announcements. The NOPC closed January 25, 2005. ANA received two public comments: One submitted by an inter-tribal non-profit organization and one from a federally-recognized tribe. The comments in response to the notice have been considered and one has been accepted. The clarification will appear in the FY 2005 SEDS, Native Language and Environmental program announcements. This notice shall

suffice as the response to comments and any public recommendations accepted by ANA will be reflected in the FY 05 program announcements to be published in the **Federal Register**.

#### *Comment and Response*

### **I. ANA Application Format**

ANA has revised Part Two, "Application Review Criteria" of the FY 2005 Program Announcement, specifically the Application Submission Requirements. Previously, ANA required applicants to include and count the Objective Work Plan (OWP) form (OMB Control Number 0980-0204), and the Federal and non-Federal share line-item budget and budget justification narrative in the page limitation. In FY 2005, ANA has removed the OWP and the line-item budget and budget justification narrative from the page limitation. With the exemption of the OWP and the budget section from the page limitation, ANA has reduced in the FY 2005 program announcements the Application Submission Requirements to 40 pages. The exemption of the OWP and the budget from the page limitation will enable applicants applying for multi-year awards to provide more information on the proposed project. (Legal authority: Section 803(a) and (d) and 803C of the Narrative American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

### **II. Required Forms**

The Grant Application Data Summary (GADS) form (OMB Clearance Number 0970 0261 exp. 03/31/2007) is a new ANA form. The Commissioner for the Administration for Native Americans is required to collect and disseminate information related to the social and economic conditions of Native Americans for inclusion in its Annual Report to Congress. The data collected on the GADS is required to assist in gathering that data. The information is also used to ensure that ANA obtains the proper number of reviewers to review each category of grant applications. Although not included in prior announcements, GADS received OMB approval after the publication of the FY 2004 announcement. It will be included in this announcement and future announcements to be submitted as a part of the application package. (Legal authority: Section 803B of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991B-2.)

### **III. Evaluation Criteria**

(a) ANA has modified five evaluation criteria titles and adjusted the point

values and weight of three criteria. In ANA's FY 2004 grant competitions, ANA did not rate applications on how closely they followed the prescribed format. This year, ANA is proposing to revise the Evaluation Criteria to provide for the award of points in rating applications based on whether the applicant complied with the requirements in the announcement with regard to the organization of the application. ANA will maintain six evaluation criteria. The title and merit weights will apply to all three ANA program areas. Criterion One was retitled from "Project Introduction and Summary/Abstract" to "Introduction and Project Summary/Application Format" and modified to add points for the Application Format to clarify the importance of adhering to the application requirements. Criterion Two was retitled from "Objectives and Need for Assistance" to "Need for Assistance". Criterion Three was retitled for clarity from "Approach" to "Project Approach". Criterion Four was retitled from "Organizational Profiles" to "Organizational Capacity" and the point value was reduced to allow for the increase in weight and points awarded under Criterion One. Criterion Five was retitled for clarity from "Results or Benefits Expected" to "Project Impact/Evaluation" and the point value was reduced to allow for the increase in weight and points awarded under Criterion Six. For FY 2005 program announcements the titles and assigned point criteria values are: Criterion One—Introduction and Project Summary/Application Format (10 pts.); Criterion Two—Needed for Assistance (20 pts.); Criterion Three—Project Approach (25 pts.); Criterion Four—Organizational Capacity (15 pts.); Criterion Five—Project Impact/Evaluation (15 pts.); Criterion Six—Budget and Budget Justification/Cost Effectiveness (15 pts.). (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

(b) In the FY 2004 Program Announcement within the ANA Criterion Five, ANA used the term "Performance" Indicator. In the FY 2005 Program Announcement this term will be changed to "Impact" Indicator to be consistent with the Native American Programs Act of 1974, as amended. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

(c) Standard and Required Impact Indicators: As ANA continues to improve its competitive grant program

ANA has modified (through addition or deletion) its collection of impact indicators under each of its programs (SEDS, Native Language and Environmental). The modified impact indicators will continue to be used to inform Congress and the public on the effectiveness, success and impact that ANA programs have in Native American communities and on behalf of Native American families. Two impact indicators will be required across all three program areas to serve as a common baseline of data that is required to be reported in ANA's legislation to demonstrate the diversity of projects and to monitor the impact of projects on the community. The FY 2005 program announcements still require five impact indicators to be submitted by the applicant under Criterion Five. ANA has standardized for consistency and program performance data collection two of the required impact indicators across all three program areas (SEDS, Native Language and Environmental). The two standard required impact indicators are: (1) Number of partnerships formed and (2) the amount of dollars leveraged beyond the required NFS match. In addition to the two standard required impact indicators, an applicant must also submit three additional indicators either selected from a suggested list in each program announcement or applicant project-specific impact indicators. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

*Discussion on Comment:* A comment was received that expressed concern about how ANA's peer reviewers would interpret ANA's standard impact indicator (2) "amount of dollars leveraged beyond the required non-federal share match". The commenter is concerned that peer reviewers will negatively perceive any leveraged resources identified by the applicant in the request for federal funds as an indication that the ANA project funds are not needed by the applicant. The commenter requested that ANA add a disclaimer to the program announcements indicating that information pertaining to leveraged resources will not be a negative factor in the review process.

*Response:* ANA annually trains peer reviewers and provides specific guidance on how to analyze proposed projects and the application scoring process as it relates to the evaluation criteria. ANA selected the "leveraged resource" indicator as a standard for all three ANA program areas because it will

yield useful information to support an analysis of how ANA's limited funding impacts native communities. The applicant's response to this indicator will also demonstrate how the leveraged resources contribute to the impact an ANA funded project has in a community. The ANA definition for "leveraged resources" is the total dollar value of all non-ANA resources that are committed to a proposed ANA project and are supported by documentation that exceed the 20% non-Federal match required for an ANA grant. Such resources may include any natural, financial and physical resources available within the tribe, organization, or community to assist in the successful completion of the project. An example would be a letter from an organization that agrees to provide a supportive action, product, and service, human or financial contribution that will add to the potential success of the project. ANA has considered the comment to add a disclaimer to the program announcements and has determined that ANA guidance and peer review procedures are sufficient to ensure a fair and reasonable review is conducted on all applications requesting federal funds. The required ANA impact indicator will remain as a standard data element to be used for ANA program data collection purposes.

The optional impact indicators for SEDS are: (1) Number of infrastructures and administrative systems, including policies and procedures developed and implemented; (2) number of codes or ordinances developed and implemented; (3) number of people to successfully complete a workshop/training; (4) number of children, youth, families or elders assisted or participating; (5) number of volunteer hours; (6) number of faith-based or community-based partnerships; (7) number of jobs created; (8) number of community-based small businesses established or expanded; (9) identification of Tribal or Village government business, industry, energy or financial codes or ordinances that were adopted or enacted; and (10) number of micro-businesses started. The optional impact indicators for Language, Category I are: (1) Number of surveys completed; (2) percent and number of community members assessed; (3) the rate of language loss or gain; (4) number of elders consulted; (5) number of language experts consulted; (6) number of community goals developed to preserve the native language; and (7) number of infrastructure and administrative systems, including policies and procedures developed and

implemented. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

The optional impact indicators for Language, Category II are: (1) Number of people involved in establishment or operation of project; (2) number of training classes or workshops held to teach language; (3) number and type of materials developed; (4) number of media products developed; (5) number of translations achieved; (6) number of individuals who increased in ability to speak the language; (7) number of participants who achieve fluency; (8) number of settings the language is spoken in; and (9) number of infrastructure and administrative systems, including policies and procedures developed and implemented. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

The optional impact indicators for Environmental are: (1) Number of environmental regulations, codes or ordinances created; (2) number of people to successfully complete a workshop/training; (3) number of workshops/trainings provided; (4) types of capacity building systems created and implemented to support environmental program functions; (5) identification of Tribal or Village government regulations, codes or ordinances that were enacted and adopted; (6) number of regulations, codes or ordinances successfully enforced; and (7) number of infrastructure and administrative systems, including policies and procedures developed and implemented. ANA may add/delete optional impact indicators to program announcements as necessary to support ANA initiatives. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2, and 2991b-3.)

*Discussion on Comment:* One comment was received that pertained to this section. The commenter suggested that ANA clarify in the evaluation criteria section the request to submit five impact indicators. The commenter offered text to clearly define the applicant's option to select three indicators from the suggested program announcement list or to submit applicant defined project indicators or to submit a combination of ANA suggested indicators and applicant defined indicators.

*Response:* ANA has reviewed the comment and concurs there is a need to

clearly describe the optional impact indicators. ANA will incorporate the following text in the three FY 2005 ANA program announcements. The following paragraph will precede the discussion on impact indicators:

In addition to the two standard required impact indicators, an applicant must also submit three additional impact indicators. These three impact indicators may be selected from the suggested list given below, or they may be developed for the specific proposed project, or the applicant may submit a combination of both the ANA suggested indicators and applicant project-specific indicators. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-2 and 2991b-3.)

(d) ANA corrected the timeframe for use of research data in an application from 48 to 36 months under the Language, Category II program.

#### IV. ANA Funding Restrictions

In ANA's effort to streamline its program announcements and to clarify Funding Restriction Policies for applicants, ANA has relocated general policy statements from the criterion section of the program announcement text to the Funding Restrictions Policies section. Formerly listed under "ANA Administrative Policies", the bullet point on funding requests for feasibility studies, business plans, marketing plans or written materials and the bullet point on proposals from consortia of Tribes were moved to the section entitled "ANA Funding Restrictions". These restrictions are already reflected in the ANA eligibility restrictions at 45 CFR 1336.33(b)(2) and (b)(6). The bullet point on the social service delivery programs was inadvertently omitted from previous announcements, but ANA is statutorily required to address these programs. The restriction already appears in the ANA eligibility regulation at 45 CFR 1336.33(b)(3). ANA will include the following funding restrictions in all program announcements in compliance with sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336:

- Projects that request funds for feasibility studies, business plans, marketing plans or written materials, such as manuals, that are not an essential part of the applicant's project or SEDS long-range development plan. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42

U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)

- The support of ongoing social service delivery programs or the expansion, or continuation, of existing social service delivery programs. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)
- Proposals from consortia of Tribes that are not specific to support from and roles of member Tribes. An application from a consortium must have goals and objectives that will create positive impacts and outcomes in the communities of its members. ANA will not fund activities by a consortium of Tribes that duplicates activities for which member Tribes also receive funding from ANA. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974 as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33.)

#### V. Initial Screening

Prior to competitive panel review, all applications are pre-screened for completeness. Previously, each application submitted to ANA in response to a program announcement was pre-screened to ensure that (a) the application was received by the program announcement closing date; (b) the application was submitted in accordance with Section IV, "Application and Submission Information"; (c) the applicant is eligible for funding in accordance with Section III, "Eligibility Information"; (d) the applicant submitted the proper supporting documentation such as proof of non-profit status, resolutions, and required government forms; (e) an authorized representative has signed the application; and (f) the applicant has a DUNS number. An application that does not meet (a) through (f) immediately above is determined to be incomplete and is excluded from the competitive review process.

In an effort to ensure consistency with the way ACF evaluates competitive discretionary grant applications, ACF has changed its policy to include only two enforceable screen-out criteria: Timeliness and compliance with stated funding limitations. Additionally, ACF has approved ANA's request to include two additional screen-out criteria: Inclusion of a signed and dated resolution by the governing body and, for applicants that are not Tribes or Alaska Native Village governments, submission of a resolution and proof that a majority of the governing board of

directors is representative of the community to be served.

Consequently, ANA will screen applications for completeness prior to the competitive panel review using the following elements: (a) The application is received by ANA on or before the published program announcement closing date; (b) the federal request does not exceed the ceiling award amount as published in the program announcement; (c) the application includes a signed and dated resolution of the governing body; and (d) if the applicant is not a Tribe or Alaska Native Village government, the native non-profit organization submits a resolution and proof that a majority of the governing board of directors is representative of the community to be served. An application that does not contain these elements will be considered incomplete and excluded from the competitive review process.

#### VI. Administrative Policies

In ANA's effort to streamline its program announcements and to clarify administrative policies for applicants, ANA has relocated general policy statements from the Criterion section of the program announcement text to the Administrative Policies section. ANA has also clarified administrative policies that have historically prompted numerous questions and created application and project development inconsistencies. For example, ANA removed "Organizational Capacity" and reworded the first bullet below for clarity. The second bullet below clarifies the administrative policy on the funding of projects versus programs to include the term "short-term" to communicate that projects will not be awarded for longer than three years in most program areas. The third and fourth bullets were moved from Definitions to Administrative Policies to establish the policy to determine project progress before additional funding is committed. For the purposes of clarify, the fifth bullet combined and reworded the requirement for community involvement under the definition for "Community Involvement" with a similar paragraph under "Need for Assistance". The sixth bullet supports the needs of ANA and was reworded for clarity. The seventh bullet was also reworded for clarity. The policy on the treatment of multiple applications and applications from Tribal components has been reworded for clarity and broken into two separate points to ensure application to both Tribes and non-profit organizations. The revised policy is contained in the eighth and ninth bullet points on the list below.

The ninth bullet corrects the inadvertent omission of the categories that apply to the board of directors for non-profit applicants. ANA will now include the following administrative policies in each program announcement (legal authority: Sections 803(a) and (d) and 803C of the native American Programs Act of 1974, as amended, and 45 U.S.C. 2991b and 2991b-3):

Applicants must comply with the following administrative policies:

- All funded applications will be reviewed to ensure that the applicant has provided a positive statement to give credit to ANA on all material developed using ANA funds.
- ANA funds short-term projects, not programs. Proposed projects must have definitive goals and objectives that will be achieved by the end of the project period. All projects funded by ANA must be completed, or self-sustaining or supported by other-than-ANA funding at the end of the project period.
- Before funding the second or third year of a multi-year grant, ANA will require verification and support documentation from the grantee that objectives and outcomes proposed in the preceding year were accomplished and that the non-federal share was met.
- ANA reviews the quarterly and annual reports of grantees to determine if the grantee is meeting its goals, objectives and activities identified in the Objective Work Plan (OWP).
- Applications from national and regional organizations must clearly demonstrate a need for the project, explain how the project originated, discuss the community-based delivery strategy of the project, identify and describe the intended beneficiaries, describe and relate the actual project benefits to the community and organization and describe a community-based delivery system. National and regional organizations must describe their membership, define how the organization operates and demonstrate Native community and/or Tribal government support for the project. The type of community to be served will determine the type of documentation necessary to support the project.
- Applicants proposing an Economic Development project must address the project's viability. A business plan, if applicable, must be included to describe the projects feasibility, cash flow and approach for the implementation and marketing of the business.
- ANA will review proposed projects to ensure applicants have considered all resources available to the community to support the project.
- ANA will not accept applications from Tribal components that are

Tribally authorized divisions unless the ANA application includes a Tribal resolution.

- ANA will only accept one application per eligible entity. The first application received by ANA will be the application considered for competition unless ANA is notified in writing which application should be considered for competitive review.

- If the applicant, other than a Tribe or an Alaska Native Village government, is proposing a project benefiting Native Americans, Alaska Natives, or both, the applicant must provide assurance that its duly elected or appointed board of directors is representative of the community to be served. Applicants must provide information that at least a majority of the individuals serving on a non-profit applicant's board fall into one or more of the following categories: (1) A current or past member of the community to be served; (2) a prospective participant or beneficiary of the project to be funded; or (3) have a cultural relationship with the community to be served. (Legal authority: 45 CFR 1336.33 (a).)

#### VII. Funding Thresholds

This is a clarification to the ANA Environmental Regulatory Enhancement program announcement funding threshold. The funding threshold for the Environmental Regulatory Enhancement program will be \$50,000.00 (floor amount) to \$250,000.00 (ceiling amount) per budget period. Applications exceeding the \$250,000.00 threshold will be considered non-responsive and will not be considered for funding under this announcement. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended 42 U.S.C. 2991b and 2991b-3.)

#### VIII. Definitions

The following definitions will be used in the appropriate program-specific FY 2005 program announcements. ANA has clarified many areas that applicants have historically found difficult to understand and that have previously prompted numerous questions and created application and project development inconsistencies. The ANA program announcements will now include additional definitions for the following terms:

*Consortium/Tribal Village:* A group of Tribes or Villages that join together for long-term purposes or for the purpose of an ANA grant.

*Impact Indicators:* Measurement descriptions used to identify the outcomes or results of the project. Outcomes or results must be

quantifiable, measurable, verifiable and related to the outcome of the project to determine that the project has achieved its desired objective and can be independently verified through ANA monitoring and evaluation.

*Objective Work Plan (OWP):* The project plan the applicant will use in meeting the results and benefits expected for the project. The results and benefits are directly related to the Impact Indicators. The OWP provides detailed descriptions of how, when, where, by whom and why activities are proposed for the project and is complemented and condensed in the OWP. ANA will require separate OWPs for each year of the project. (Form OMB# 0980-0204 exp 10/31/2006.)

*Minor Renovation or Alteration:* Work required to change the interior arrangements or other physical characteristics of an existing facility, or install equipment so that it may be more effectively used for the project. Minor alteration and renovation may include work referred to as improvements, conversion, rehabilitation, remodeling or modernization, but is distinguished from construction and major renovations. A minor alteration and/or renovation must be incidental and essential for the project ("incidental" meaning the total alteration and renovation budget must not exceed the lesser of \$150,000 or 25 percent of total direct costs approved for the entire project period).

*Total Approved Project Costs:* The sum of the Federal request plus the non-Federal share. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

#### IX. Application Review Information

To ensure that grantees fulfill their obligations to ANA, ANA is including a review of grantees' past performance when considering the applicant for a new or ongoing award under all three program areas. The inclusion of this item in the application consideration process will assist ANA in making its funding decisions on whether or not to award to a particular grant applicant. Factors that may impact a grantee's past performance are their timeliness to report submission requirements, timely use and proper expenditure of the grant award funds and the administrative ease of closing out the grantee at the end of the award period.

The following statement is included under the Application Consideration for the Review and Selection Process:

*Application Consideration:* The Commissioner's funding decision is

based on an analysis of the application by the review panel, panel review scores and recommendations; an analysis by ANA staff; review of previous ANA grantee's past performance; comments from the State and Federal agencies having contract and grant performance-related information; and other interested parties.

#### X. Native Language Program Area

The title for Native Language Category I grants has been changed from "Native Language Category I Planning" to "Native Language Category I Assessment". The change clarifies the purpose of the 12-month Category I grant. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

The FY 2005 Native Language Program Announcement expands the Category I-Program Area of Interest and the necessary assessment data to be collected. ANA recommends each applicant consider the Program Area of Interest in the development of a project. The Program Area of Interest under Category I is "A project for data collection and compilation that surveys the current language status through a "formal" method (e.g., work performed by a linguist and/or a language survey conducted by community members) or an "informal" method (e.g., a community consensus of the language status based on elders, Tribal scholars and/or other community members) with the development of long-range language preservation goals and uses elders in the development of these goals. This assessment data should capture, at a minimum, the following data: Number of speakers; age of speakers; gender of speakers; level(s) of fluency; number of first language speakers (native language as the first language acquired); number of second language speakers (native language as the second language acquired); where native language is used (e.g., home, court system, religious ceremonies, church, media, school governance or cultural activities); source of data (formal and/or informal); and rate of language loss or gain. (Legal authority: Section 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

#### Additional Information

*Technical Correction:* Upon general review of the Notice, Section V: Screening Elements, item "d" will be rewritten as "Each application submitted under an ANA program announcement will undergo a pre-review screening for:

\* \* \* (d) if the applicant is not a Tribe or Alaska Native Village government, the applicant must submit proof that a majority of the governing board of directors is representative of the community to be served." The reference to Native non-profit organizations was inadvertently placed in the text. This correction will be reflected in all three FY 05 ANA program announcements.

*Technical Correction:* Upon general review of the Notice, Section II. Evaluation Criteria (a) additional text is needed to clarify the use of the ANA Project Abstract form in relation to Criteria One: Introduction and Project Summary/Application Format. Instructional text will be inserted in the ANA evaluation Criterion One to state "In addition to using the ANA Project Abstract form, applicants will submit a brief narrative summary of the project that provides more information on the applicant and proposed project." The additional text will provide clarity to the applicant as they respond to the program announcement.

Dated: January 31, 2005.

**Quannah Crossland Stamps,**

*Commissioner, Administration for Native Americans.*

[FR Doc. 05-2325 Filed 2-7-05; 8:45 am]

BILLING CODE 4184-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0016]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs: Study 1**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of consumer evaluations of various consumer-friendly formats for the brief summary in direct-to-consumer

(DTC) prescription drug print advertisements.

**DATES:** Submit written or electronic comments on the collection of information by April 11, 2005.

**ADDRESSES:** Submit electric comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** 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 each of 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.

**Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs: Study 1**

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act. Under the act, a drug is misbranded if its labeling or advertising is false or misleading. In addition, section 502(n) of the act (21 U.S.C. 352(n)) specifies that advertisements for prescription drugs and biological products must provide a true statement of information "\*\*\*\*in brief summary\*\*\*\*" about the advertised product's "\*\*\*\*side effects, contraindications and effectiveness\*\*\*\*." Generally, the display text of an advertisement presents a fair and balanced disclosure of the product's indication and benefits and the product's side effects and contraindications. The prescription drug advertising regulations (§ 202.1(e)(3)(iii) (21 CFR 202.1(e)(3)(iii))) specify that the information about risks must include each specific side effect and contraindication" from the advertised drug's approved labeling. The regulation also specifies that the phrase "side effect and contraindication" refers to all of the categories of risk information required in the approved product labeling written for health professionals, including the Warnings, Precautions, and Adverse Reactions sections. Thus, every risk in an advertised drug's approved labeling must be addressed to meet these regulations.

In recent years, FDA has become concerned about the adequacy of the brief summary in DTC print advertisements. Although advertising of prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. Results of the FDA 2002 survey on DTC advertising (available at [www.fda.gov/cder/ddmac/researchka.htm](http://www.fda.gov/cder/ddmac/researchka.htm)) provide some information regarding the extent to which consumers read these ads and the brief summary that accompanies the main ad—41 percent of respondents in 2002 reported they do not usually read any of the brief summary. Use of the brief summary was a function of whether they have an interest in the