the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF 118–A, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the Tribal child care program. The ACF 118–A is currently approved through May 31, 2014, making it available to Tribes needing to submit Plan Amendments through the end of the FY 2013 Plan Period. However, on July 1, 2013, Tribes will be required to submit their FY 2014–2015 Plans for approval by September 30, 2013. Consistent with the statute and regulations, ACF requests revision of the ACF 118–A with minor corrections and modifications.

The Office of Child Care (OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

Respondents: Tribal CCDF programs (257 total).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	257	0.50	120	15,420

Estimated Total Annual Burden Hours: 15,420.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–04421 Filed 3–25–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA numbers 93.581, 93.587, 93.612]

Request for Public Comment on the Proposed Adoption of Administration for Native Americans Program Policies and Procedures

AGENCY: Administration for Native Americans, ACF, HHS.

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans (ANA) is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules, general statements of 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. In accordance with notice requirements of NAPA, ANA herein describes its proposed interpretive rules, general statements of policy, and rules of agency procedure or practice as they relate to the Fiscal Year (FY) 2013 Funding Opportunity Announcements (FOA) for the following programs: (1) Social and Economic Development Strategies (hereinafter referred to as SEDS); (2) Native Asset Building Initiative (hereinafter referred to as NABI); (3) Sustainable Employment and Economic Development Strategies (hereinafter referred to as SEEDS); (4) Native Language Preservation and Maintenance (hereinafter referred to as Language Preservation); (5) Native Language Preservation and Maintenance—Esther Martinez Initiative (hereinafter referred to as Language—EMI); and 6) Environmental Regulatory Enhancement (hereinafter referred to as ERE). This notice of public comment also provides additional information about ANA's plan for administering the programs.

DATES: The deadline for receipt of comments is 30 days from the date of publication in the **Federal Register**.

ADDRESSES: Comments in response to this notice should be addressed to Lillian A. Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade SW., Mail Stop: Aerospace 2—West, Washington, DC 20447. Delays may occur in mail delivery to federal offices; therefore, a copy of comments should be faxed to (202) 690–7441. Comments will be available for inspection by members of the public at the Administration for Native Americans, 901 D Street SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, ANA (877) 922–9262.

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, requires ANA to provide notice of its proposed interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice. The proposed clarifications, modifications, and new text will appear in the six FY 2013 FOAs: SEDS, NABI, SEEDS, Language

Preservation, Language—EMI, and ERE. This notice serves to fulfill this requirement.

A. Funding Opportunity Announcements: For information on the types of projects funded by ANA, please refer to ANA's Web site for information on our program areas and funding opportunity announcements: *http://www.acf.hhs.gov/programs/ana.*

The following changes will be made to ANA's FOAs this year:

1. In FY 2013, ANA proposes discontinuing the practice of publishing a separate SEDS—Tribal Governance FOA (HHS–2012–ACF–ANA–NG–0278) and, instead, incorporating the Tribal Governance program areas of interest into the annual SEDS FOA. Also, ANA proposes adding responsible fatherhood as a program area of interest under the annual SEDS FOA.

Additionally, ANA proposes adding two new program areas of interest to the annual SEDS FOA focused on suicide prevention and on human trafficking. Based on information gathered during tribal consultation sessions and at other meetings, the ANA Commissioner has been asked to address the issues related to suicide with which many Native communities are grappling, as well as with issues related to human trafficking that can occur on remote, isolated lands, and among vulnerable populations.

Under SEDS, ANA proposes to move the following four sub-program areas of interest out of Economic Development: (1) Emergency preparedness, (2) economic competitiveness, (3) agriculture, and (4) commercial trade. Emergency preparedness will be included under the governance program area of interest under the SEDS FOA. Economic competitiveness, agriculture and commercial trade will move to a proposed new FOA that is to be known as Sustainable Employment and Economic Development Strategies (SEEDS) (HHS–2013–ACF–ANA–NE–0588), which is part of the SEDS program (see proposal #2 in this section). For additional information on this proposed FOA, you may also refer to the concept paper located at the following link: *http://www.acf.hhs.gov/programs/ana/resource/proposed-seeds-foa-concept-paper.* (Legal authority: Section 803(a) of NAPA, as amended).

2. In FY 2013, ANA will introduce the SEEDS FOA that will focus on developing employment opportunities and business creation in Native communities. These types of projects were formerly funded under the SEDS FOA. ANA will expand funding for new, community-based projects that will foster economic development through the creation of small businesses and sustainable job growth, which will be funded under the same Catalog of Federal Domestic Assistance (CFDA) number as SEDS. The current economic climate has increased ANA's focus on developing employment opportunities and business creation in native communities, resulting in this special funding initiative to promote SEEDS. In an effort to reduce unemployment and stimulate local economies, ANA will make $5,000,000 available for SEEDS funding in FY 2013 for new, community-based projects that will foster economic development through the creation of small businesses and sustainable job growth. Applicants eligible for the SEEDS FOA are the same as those identified as eligible for SEDS though current SEDS grantees with grants that will go beyond the start date of the possible new award are not eligible for funding under SEEDS.

Four priorities that ANA will promote through the SEEDS initiative are: (1) Creation of sustainable employment opportunities; (2) professional training and skill development that increases participants' employability and earning potential; (3) creation and development of small businesses and entrepreneurial activities, and; (4) demonstrated strategy and commitment to keeping the jobs and revenues generated by project activities within the native communities being served. Improving access to employment opportunities and supporting small businesses will enhance local economies, enable more tribal members to acquire and maintain gainful employment, and improve the long-term financial health of tribal members and their families.

ANA has identified the following program areas of interest for the SEEDS FOA, however funding is not restricted to those listed below:

(a) *Agriculture:* Creating, developing, or enhancing agricultural enterprise and sustainable farming projects with a focus on distribution at local and commercial markets.

(b) *Career Pathways:* Using multi-sector partnerships with entities such as Tribal Colleges, workforce development agencies, social service providers, and employers to develop workforce training programs that respond to local employers' hiring needs.

(c) *Commercial Trade:* Strengthening local economies by increasing the demand for locally produced goods and services.

(d) *Economic Competitiveness:* Creating, expanding, and retaining businesses to reflect distinct economies operating in rural and urban areas, in both mature and emergent sectors.

(e) *Economic Infrastructure:* Addressing economic infrastructure needs that will strengthen business development and job creation in native communities.

(f) *Entrepreneurship and Microbusiness:* Promoting entrepreneurial development through business incubators and other activities that support businesses and market the availability of local products or services. (Microbusiness loans will not be available under such projects.)

(g) *Local Sourcing and Technology:* Using new technologies to enhance distribution channels for locally produced goods and services.

(h) *Professional Development:* Providing professional training, skill development (including soft skills, basic skills, or technical skills) or certification that will enhance participants' employment and earning prospects.

(i) *Interoperability/Integration (partnering with ACF programs and clients):* Helping ACF clients such as youth aging out of foster care, TANF or TANF eligible individuals, or noncustodial parents with child support agreements to obtain employment.

(j) *Place-based Strategies:* Using a tribe or community's local or regional assets and resources and collaborating with multiple stakeholders to address economic development barriers.

3. The program areas of interest will remain the same for the following ANA FOAs: Native American Language Preservation and Maintenance (HHS–2011–ACF–ANA–NL–0139); Native American Language Preservation and Maintenance—Esther Martinez Initiative (HHS–2011–ACF–ANA–NL–0140); Environmental Regulatory Enhancement (HHS–2011–ACF–ANA–NR–0142), and Native Asset Building Initiative (HHS–2013–ACF–ANA–NO–0587).

B. Administrative Policies: ANA proposes revising all funding opportunity announcements to include three new administrative policies, remove one administrative policy used in prior years, and will clarify another administrative policy, as follows:

1. Proposal: All applicants must submit documentation, such as a resolution, demonstrating that the governing body of the organization approves the application's submission to ANA for the current grant competition period. In addition, if the applicant is a tribally-authorized component or division, the applicant must also include a resolution demonstrating that the governing body of the tribe approves the application's submission to ANA for the current competition period. All resolutions must be signed by an official of the

governing body and dated. In lieu of a resolution, meeting minutes from the governing body and/or a letter from the current tribal leader may be acceptable forms of documentation if that is more appropriate to that tribal government structure. The documentation should be included with the application's submission to ANA. Project funds will not be awarded without ANA's receipt of signed and dated documentation prior to the start of the project period.

Rationale: The NAPA requires that a governing body ''has not disapproved'' the project ''within 30 days of its submission'' to the governing body (42 U.S.C. 299f(1)). Therefore, ANA's administrative policy is included to ensure that funded applications are supported by the governing body of the tribe or organization. In previous FOAs, lack of such resolutions as part of the application submission has been a disqualification factor that resulted in the elimination of many applications from the competitive review process. The requirement for evidence that the governing body has either affirmatively approved or not disapproved the project remains the same; however, it is no longer required by the due date of the FOA in which an application was submitted. In lieu of a resolution, meeting minutes from the governing body and/or a letter from the current tribal leader may be acceptable forms of documentation if that is more appropriate to that tribal government structure. It is important that the tribal leadership is aware of its fiscal responsibility and potential for financial liabilities in administering the ANA program. The change of administrative policy is recommended in order to increase the number of applications that are eligible for the competitive review process. If an application is ranked within funding range but does not include a governing body's resolution, ANA staff will require this documentation in advance of making a grant award.

2. Proposal: Grantees will be required to attend Post Award Training during the first year of their ANA award, and to attend an annual ANA Grantee Meeting during each year of their ANA award. Therefore, applicants will be required to include an appropriate amount for travel costs to attend Post Award Training in the first year of the proposed project budget, and travel costs to attend the annual ANA Grantee meeting for each year of the proposed project's budget. Also, participation and attendance at Post Award Training and the ANA Grantee Meeting should be included activities within each year of the project's Objective Work Plan (OWP). See *Section IV.2. Content and Form of Application Submission, Project Budget and Budget Description,* for specific travel costs that should be included to attend Post Award Training, to be held in the grantee's region, and the ANA Grantee Meeting, which is usually held in Washington, DC.

Rationale: This policy is added to ensure that applicants understand the mandatory training meeting and budgetary requirements for an ANA grant. By including this under the administrative policies instead of evaluation criteria, ANA believes confusion by panel reviewers will be eliminated thus ensuring panel reviewers do not score an application based on the inclusion or omission of these trainings in their budget and OWP.

3. Proposal: Under the standard terms and conditions for discretionary HHS awards (Grants Policy Statement, page II–7 at *https://www.acf.hhs.gov/grants/terms-and-conditions*), grant recipients are required to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. Therefore, staff employed through an ANA-funded project cannot also serve as a member of the governing body for the applicant organization. During the award negotiation phase, ANA will ask the prospective recipient to modify project personnel if a proposed staff member is also a member of the applicant organization's governing body. In addition, there should be a separation of duties from staff and the governing bodies within an organization to ensure the integrity of internal controls and to minimize disruptions in the continuity of operations.

Rationale: This policy has been added to remind applicants of the requirement to establish safeguards that prohibit employees from using their positions for a purpose that presents a conflict of interest or the appearance of a conflict of interest. An applicant organization must also have auditable internal controls in place to ensure the integrity of the management of federal funds. In recent years, ANA has seen challenges arise with grantees in which individuals are dually serving as paid staff and also as a member of the recipient organization's Board of Directors.

Additionally, ANA proposes to eliminate the administrative policy previously stated in *Section I, Funding Opportunity Description, Administrative Policies,* which requires the submission of a business plan. However, submission of a business plan will remain a requirement for the submission of certain economic development projects as stated in *Section IV.2, The Project Description.*

C. Disqualification Factors: ANA proposes revising the disqualification factors that are specific to applications submitted for ANA funding. ANA will remove a previously identified disqualification factor, clarify an existing factor, and add a new disqualification factor. (Legal authority: Section 803(a) and 814 of NAPA, as amended).

1. Board Resolution

All applicants must submit a resolution demonstrating that the applicant's official governing body approves the application submission to ANA for the current grant competition period. In addition, if the applicant is a tribally authorized component or division, the application must also include a resolution demonstrating that the governing body of the Tribe approves the application submission to ANA for the current competition period. Applicants that do not include this documentation will be considered non-responsive, and the application will not be considered for competition.

ANA proposes removing the disqualification factor associated with the submission of an approved board resolution. ANA will still require that this documentation be submitted but it will now be designated as an administrative policy (see administrative policies above for additional clarification). All applicants must submit documentation, such as a resolution, demonstrating that the governing body of the organization approves the application's submission to ANA for the current grant competition period. In addition, if the applicant is a tribally-authorized component or division, the applicant must also include a resolution demonstrating that the governing body of the tribe approves the application's submission to ANA for the current competition period. All resolutions must be signed by an official of the governing body and dated. Project funds will not be awarded without the submission of signed and dated documentation prior to the start of the project period. Applications received without the required governing body's resolution will no longer be disqualified from competitive review.

2. Governing Body Documentation

This disqualification factor applies only to applicants that are not Tribes or Native Alaska villages. Organizations applying for funding must show that a majority of board members approving the project proposal are representative of the community to be served. The applicant should submit documentation that identifies each board member by name and indicate their affiliation or relationship to at least one of the four categories of representation listed in the factor. ANA revised the categories of representatives of the community to be served to include: (1) members of Federally or State recognized Tribes; (2) persons eligible to be a participant or beneficiary to the project to be funded; (3) persons who are recognized by the eligible community to be served as having a cultural relationship with the community to be served; or (4) persons considered to be Native American as defined in 45 CFR 1336.10 and Native American Pacific Islanders as defined in the Native American Programs Act. Applicants that do not include this documentation will be considered non-responsive, and the application will not be considered for competition.

This disqualification factor will remain in effect but is clarified. ANA proposes to add clarification to this disqualification factor to indicate that the documentation that must be submitted identifies each board member by name and indicates their relationship to at least one of the four categories of representation listed in the factor. Applications that are submitted without this documentation will be considered non-responsive to the FOA and will not be considered for competition. (Legal authority: Section 803(a) and 814 of NAPA, as amended.)

3. Only One Active Award per CFDA

This disqualification factor applies to all types of eligible applicants. Organizations can have no more than one active award per CFDA number for an ANA program at any given time. Therefore, organizations that have a current ANA grant that is eligible for a Non Competing Continuation (NCC) award which: A) will go beyond the start date of the possible new award, and B) was awarded under the same CFDA number as this FOA, will not have their applications considered for the competition. This disqualification factor is based on the administrative policy that prohibits grantees from having more than one active grant per CFDA number. This disqualification factor does not apply to organizations eligible for an NCC award for the continuation of an ANA grant made under a different CFDA number (funding opportunity announcement).

Under the Administrative Policies, ''Grantees can have only one active grant award per Catalog of Federal Domestic Assistance (CFDA) number.'' ANA is proposing that this policy should also become a disqualification factor that will apply to all applicants. The limit of one active award per CFDA number has been a long-standing ANA policy that was implemented to ensure a wider distribution of ANA's federal funding. ANA strongly believes in maximizing the beneficial use of its limited funding for the greatest number of people in the targeted communities. By including this administrative policy as a disqualification factor, ANA will screen-out from competition those applications submitted by an applicant that would be ineligible for funding because the organization has an ongoing ANA award funded by the same CFDA number that will continue past the start date of the new award.

Previously, ANA has had to expend its limited resources to review all grant applications, even if the applicant was likely not to receive an award based on the administrative policy. If the application was found to be within the funding range, the application was ultimately not funded. Under the disqualification factor, applications from existing grantees with an award that has the same CFDA number will be screened out of competition and the application will not be reviewed. Therefore, applicants should be cautioned to not apply for a new grant that has the same CFDA number if they have a concurrent ANA award. For example, applicants with a current ANA grant that is eligible for a Non-Competing Continuation (NCC) award that will extend beyond the start date of the new award offered under the FOA, and was awarded under the same CFDA number as that of the current FOA, will be disqualified from the competitive review. This disqualification factor is based on the administrative policy that prohibits grantees from having more than one active grant per CFDA number. See *Section I. Funding Opportunity Description, Administrative Policies.*

D. Definitions: ANA is adding a definition for ''impact indicator'' in all FY 2013 FOAs. (Legal authority: Section 803(b) and 814 of NAPA, as amended and 42 U.S.C. § 2991b–3(b)(7)(C).

1. *Impact Indicator:* A quantitative measure used to monitor a project's progress in achieving its intended outcomes and impact. An impact indicator should identify the extent to which a project's overall desired outcome was achieved and should describe how the conditions discussed in the Need for Assistance were changed as a result of the project. For example, a project focused on healthy relationships would likely use the community's divorce rate as an impact indicator.

E. Do Not Fund: ANA will add the following five project types that it will not fund to *Section V.2. Review and Selection Process.* These projects will not be disqualified from competitive review but ANA reserves the right not to fund them regardless of the outcome of panel review.

1. Projects that do not demonstrate that the proposed staff or organization has the required expertise, or organizational capacity, to fulfill the project approach or to achieve the stated objectives or outcomes of the application.

ANA applicants should provide evidence that the applicant organization, and any partnering organizations, have relevant experience and expertise with administration, development, implementation, and management of programs similar to that proposed in order to fulfill the project's approach. ANA has received some applications that scored within the funding range but did not demonstrate that the organization had sufficient capacity or staffing expertise to implement the proposed project, nor had the applicant identified partnerships that would assist them in achieving the project's objectives. Funding these types of applications would not be the best use of ANA's limited resources or taxpayer dollars.

2. Projects with the potential to cause unintended harm or that could negatively impact the safety, or privacy, of individuals.

This ''Do Not Fund'' is added to ensure that projects funded by ANA will not cause harm or impact the safety, or privacy, of individuals. ANA has received several applications proposing activities that could cause harm, including the use of inaccurate medical information in health counseling, purchasing surveillance equipment to monitor tribal citizens, or proposing potentially dangerous activities involving youth. One of ANA's goals is to safeguard the health and well-being of Native children and families; therefore, ANA reserves the right to not award federal funds for activities that may adversely impact the safety or well-being of Native people in their communities.

3. Applications for proposed projects that are not written specifically in response to an ANA FOA. These applications may have been submitted to another funding agency and are not tailored to ANA's goals as specified in an ANA FOA.

This ''Do Not Fund'' will be added to ensure that proposed projects are specific to ANA's funding goals and that they are strongly supported by the community. ANA has previously received applications that include

letters of support that were written to other funding agencies and are not specific to the project proposed for ANA funding. This does not demonstrate a strong commitment towards fulfilling the purpose of ANA's goals and is not specific to the requirements of ANA's FOAs.

4. Projects that do not demonstrate a current need or recent community support for the proposed project.

This ''Do Not Fund'' area is to ensure that the applicant has worked with its community within the last three years (or sooner) to identify the need for the project and to obtain their input or involvement in the planning for the proposed project. Based on internal reviews of grantees' impact evaluations, ANA has discerned that strong community support for projects in advance of funding, and throughout the project's implementation, is integral to the success of an ANA-funded project. For example, if an applicant proposes to address a need that was identified as part of a tribe's 10-year strategic plan, which was completed 7 years ago, the applicant should demonstrate that the need still remains and that more recent interactions and input from the community have been part of the project's planned approach.

5. Projects that may be used for the purpose of providing loan capital. Federal funds awarded under this FOA may not be used for the purpose of providing loan capital. This is not related to loan capital authorized under Sec. 803A of NAPA [42 U.S.C. 2991b–1(a)(1)] for the purpose of the Hawaiian Revolving Loan fund.

This ''Do Not Fund'' will be added to clarify ANA's interpretation of the NAPA on the use of ANA funding for loan capital purposes. ANA will not fund projects which propose activities that include the use of grant funds as loans.

F. Page Limits: In *Section IV.2. Content and Form of Application Submission, Formatting ACF Applications,* ANA will implement a maximum page limit for all applications for FY 2013.

1. Total application: ANA will implement a total page limit of 150 pages for applications submitted in response to the FOA for SEDS, Language Preservation, Language—EMI, and ERE programs, and a 200 page limit for applications submitted in response to the NABI and SEEDS programs. Additional pages will be allowed for NABI applications due to a required five-year project period and the submission of two budgets and two budget justifications. Additional pages will be allowed for SEEDS applications due to project periods lasting up to five years. The page limitation excludes a Business Plan (if applicable) or mandatory grant forms (Standard Forms and ANA's Objective Work Plan form). Applications that exceed the page limits will have excess pages removed prior to the application's panel review.

G. Project Description: ANA will make modifications to the project description narrative.

1. Letters of Support: ANA has added Letters of Support as a requirement. Applicants should provide statements from community, public, and commercial leaders that support the project proposed for funding. All submissions must be included in the application package.

2. Third-party agreements: ANA has added third-party agreements as a requirement. Third-party agreements include Memoranda of Understanding (MOU) aka Letters of Commitment. General letters of support are not considered to be third-party agreements. Third-party agreements must clearly describe the project activities and support to which the third party is committing. Third-party agreements must be signed by the person in the third-party organization with the authority to make such commitments on behalf of their organization. Applicants should provide written and signed agreements between grantees and subgrantees, or subcontractors, or other cooperating entities. These agreements must detail the scope of work to be performed, work schedules, remuneration, and other terms and conditions that structure or define the relationship.

3. Budget and Budget Justification:

Travel: Text will be added requiring applicants to include costs in their budget for mandatory post-award travel for training and the ANA Grantee Meeting. Additional information will be provided within the FOA on estimated costs based on applicant's regional location.

H. ANA Application Evaluation Criteria: ANA will revise the evaluation criteria for the SEDS, Language Preservation, Language—EMI, and ERE FOAs to allow greater flexibility in applicants' proposals. The evaluation criteria will be revised to include clearer explanations of how ANA will assess the information provided in the applications. (Legal authority: Section 803(c) of NAPA, as amended.) The evaluation criteria for NABI will not be changed.

1. Titles and Assigned Weight: In FY 2013, ANA will increase the number of evaluation criteria from four to five and adjust the weighted scores to focus on those elements that are important to project success and project monitoring. Weighted sub-criteria scores are identified for the ''Project Approach'' criterion only.

For SEDS, Language Preservation, Language—EMI, and ERE FOAs published in FY 2013, the criteria will be weighted as follows:

Project Integration—10 points;
Objectives and Need for Assistance—10 points;
Project Approach—50 points;
Sub criterion—Project Strategy—30 points
Sub criterion—Objective Work Plan—20 points
Outcomes Expected—20 points
Budget and Budget Justification—10 points

2. ANA Evaluation Criteria: Included here is a summary of the changes made to the criteria.

(a) Project Integration: ANA will add a new criterion entitled, ''Project Integration,'' that will score how well the application ties together the proposed project through the other four criteria. The overall point value for this section will be 10 points. To score the Project Integration criterion, reviewers will consider the extent to which all the application criteria elements are aligned, i.e., how effectively the Objectives and Need for Assistance, Project Approach, Budget, and Outcomes Expected complement one another into a cohesive and carefully planned project. For example, if the application's proposed project description was a jigsaw puzzle, how well do the puzzle pieces fit together? This criterion does not measure any element of the application in isolation and does not respond to a specific information request concerning project integration.

(b) Objectives and Need for Assistance: The overall point value has been decreased to 10 points due to the addition of the project integration criterion.

(c) Outcomes Expected: The overall point value for this section has been increased to 20 points to emphasize the importance of applicants connecting their proposed project's goal, objectives, and activities to the intended results, benefits, and impacts produced by the project.

(d) Budget and Budget Justification: The overall point value for this section has decreased to 10 points due to the addition of the project integration criterion.

The changes to the content of evaluation criteria, and the complementary changes to the project

description section of the FOA, will more effectively guide applicants and panel reviewers on what ANA believes are critical components of a project's application. (*Legal authority:* Section 803(c) of NAPA, as amended.)

I. Objective Review and Results: ANA's FOA currently states ''Results of the competitive objective review are taken into consideration by ACF in the selection of projects for funding; however, objective review scores and rankings are not binding. They are one element in the decision-making process.'' ANA will clarify the scoring process in this section by stating that ANA will have the discretion to Use either the actual ''raw'' score or a normalized score in order to determine the ranking of applications after the panel review has been completed. The raw score is the average of the actual scores given by the three panelists that served as peer reviewers for the application. A normalized score is a statistical method that accounts for the variability and relative nature of individual reviewers' scoring tendencies. Normalized scores are used to counteract any possible predisposition or scoring biases of individual reviewers and panels in order to make the outcome fairer for all applications. The use of a normalized score is allowable and authorized by HHS grants administration policy.

Lillian A. Sparks,

Commissioner, Administration for Native American.

[FR Doc. 2013–04383 Filed 2–25–13; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0172]

Agency Information Collection Activities: Proposed Collection; Comment Request; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in FDA's regulations on foreign clinical studies not conducted under an investigational new drug application (IND).

DATES: Submit either electronic or written comments on the collection of information by April 29, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* 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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

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 reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Foreign Clinical Studies Not Conducted Under an IND—(OMB Control Number 0910–0622)—Reinstatement

Under 312.120 (21 CFR 312.120), FDA accepts foreign clinical studies not conducted under an IND as support for an IND or application for marketing approval for a drug or biological product if the studies are conducted in accordance with good clinical practices (GCP), including review and approval by an independent ethics committee (IEC).

Under § 312.120(a), FDA accepts as support for an IND or application for marketing approval a well-designed and well-conducted foreign clinical study not conducted under an IND if the study is conducted in accordance with GCP, and we are able to validate the data from the study through an onsite inspection if necessary. GCP includes review and approval by an IEC before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject before initiating a study.

Under § 312.120(b), a sponsor of a non-IND foreign study who wants to rely on that study as support for an IND or application for marketing approval must provide the following information to FDA: (1) The investigator's qualifications; (2) a description of the research facilities; (3) a detailed summary of the protocol and results of the study and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records; (4) a description of the drug substance and drug product used in the study, including a description of the components, formulation, specifications, and, if available, bioavailability of the specific drug product used in the clinical study; (5) if the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126; (6) the name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 312.3; (7) a summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion; (8) a description of how informed consent was obtained; (9) a description of what incentives, if any,