

March 8, 2004—9:30 a.m.—4 p.m. ....	Westin Crown Center, 1 Pershing Road, Kansas City, MO 64108, Meeting Room: Pershing Place West.	Kansas City, MO.
March 9, 2004—9:30 a.m.—4 p.m. ....	Hilton Jacksonville, 1201 Riverplace Blvd., Jacksonville, Florida 32207, Meeting Room: St. Johns.	Jacksonville, FL.
March 9, 2004—9:30 a.m.—4 p.m. ....	Radisson Hotel Toledo, 101 North Summit Street, Toledo, Ohio 43604, Meeting Room: Ballroom 1.	Toledo, OH.
March 10, 2004—9:30 a.m.—4 p.m. ....	Positively Oak Cliff, 3107 West Camp Wisdom Road, Suite 980, Dallas, TX 75237.	Dallas, TX.
March 10, 2004—9:30 a.m.—4 p.m. ....	NJ Department of Corrections, Central Office, Stuyvesant Ave. & Whittlesey Road, Trenton, New Jersey 08625.	Trenton, NJ.

Interested parties should contact Susan Spanguolo; MANY; 135 Cumberland Road; Suite 201 Pittsburgh, PA 15237; 412-366-6562; 412-366-5407 fax; [susan@manynet.org](mailto:susan@manynet.org) to register for the meeting.

Dated: March 2, 2004.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 04-5132 Filed 3-5-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Administration for Native Americans (ANA); Adoption of ANA Program Policies and Procedures

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Native Americans (ANA) herein issues 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.

**EFFECTIVE DATE:** December 21, 2003.

**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, under the statute, 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.

ANA published a Notice of Public Comment (NOPC) in the **Federal Register** (68 FR 64685) on November 14, 2003 on the proposed ANA policy and program clarifications, modifications, and activities for FY 2004. The NOPC closed December 14, 2003. ANA received comments from three different entities: (A) one comment was submitted from an Alaska Village Council; (B) three comments were received from a national Native American non-profit organization, and (C) several editorial comments were received from an individual. ANA has considered all the public comments received and has included clarifications and modifications reflecting several of the comments in the SY 2004 SEDS, Native Language and Environmental Program Announcements.

#### Final Policies and Procedures and Comments and Responses

##### 1. Policy on Deadline Date for Applications

For FY 2004, ANA will have one closing date for the SEDS Program or other special initiative undertaken pursuant to Section 803(a) of the Native American Programs Act of 1974, 42 U.S.C. 2991b, and one closing date each for the Alaska SEDS Program, Native Language program, and the Environmental program. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1972, as amended, 42 U.S.C. 2991b and 2991b-3*)

##### 2. Receipt of Applications

ANA's program announcements will now require that all applications for funding be "received by" ANA by the closing date. Consistent with past practices, ANA will not acknowledge receipt of applications. Previously, ANA accepted applications for funding if they were postmarked on or before the closing date. The change to receipt of the application by the closing date is expected to reduce disputes regarding postmarks and late-arriving applications. This change will also ensure ANA has the appropriate number

of skilled peer panel reviewers available to review submitted applications. Applications received after the published closing date as stipulated in this published announcement will not be considered. The new program announcement closing schedules will allow ANA to release all funding to communities earlier in the fiscal year; provide applicants additional time to receive agency comments and seek free technical assistance before the next competition in the program. Additionally, ANA grantees will have the opportunity to implement projects in a timely manner, recruit personnel to support the grantee's objectives; and decrease the number of requests for no cost grant extensions. This modification will afford ANA the opportunity to perform grant administration and program monitoring and evaluation activities that support new and non-competing continuation grants. (*Legal authority: Sections 833(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

*Discussion of Comment:* The one comment received on this section expressed concern with the change associated with the receipt of applications from "postmarked by" to "received by." The commenter expressed concern that unreliable mail service delivery from remote areas will cause undue stress on organizations.

*Response:* During the previous competitive cycle, ANA performed an assessment of all phases and benchmarks of the pre-award process to determine areas of needed efficiency. The determination to change from "postmarked by" to "received by" was given much consideration, especially considering some ANA applicants are located in isolated communities. This policy will be an adjustment for all applicants, however the outcomes of improved reader selection, the elimination of disputes associated with postmarks and late-arriving applications, and other pre-award activities are more beneficial to applicants than the re-instatement of the "post-marked by" policy. ANA intends to have the program announcements

published with sufficient time allowed for applicants to prepare and submit an application in a timely manner. Therefore, the requirement for applications receipt will remain intact.

### 3. Access to Program Announcement and Application Materials

The program announcement and the application materials are available on the ANA Web site at: <http://www.acf.hhs.gov/programs/ana>. The material on the Web site is provided as information only. ANA makes all reasonable efforts to assure that the Web site is complete and accurate. The applicant bears sole responsibility, to assure that the copy downloaded and/or printed from any source is accurate and complete. In case of a conflict between the content of material downloaded from the website and the material appearing in the **Federal Register**, the notice published in the **Federal Register** shall take precedence. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 4. Application Submission Requirements

The format of the application for funding is now standardized. The new application format will help applicants focus on the type of information and data required to support an application for funding. ANA will implement a page limitation requirement to enable a thorough review of the application. (See 4(a) and (b)). ANA will implement these page requirements with a limit on the number of pages for each section. These modifications to the announcement will reduce the amount of documentation applicants need to submit and it will both strengthen and streamline the peer panel review process to allow reviewers to focus on the project and applications content. Additionally, program announcement standardization will prepare ANA and applicants for the Federal Government's Electronic Grant Application submission initiative and process. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

4. (a) *Organization and Preparation of Application:* Due to the intensity and pace of the application review and evaluation process, ANA has standardized the application submission format. The new application submission format for the SEDS program is included in this notice.

4. (b) *ANA Application Format:* ANA will now require all applications to be

labeled with a Section Heading in compliance with the format provided in the program announcement. This format applies to all applicants submitting applications for funding in the programs covered by this notice. All pages submitted (including Government Forms, certifications and assurances) should be numbered consecutively. The paper size shall be 8 1/2 x 11 inches, line spacing shall be a space and a half (1.5 line spacing), printed only on one side, and have a half-inch margin on all sides of the paper. The font size should be no smaller than 12-point and the font type shall be Times New Roman. These requirements do not apply to the project Abstract Form, Letters of Commitment, the Table of Contents, and the Objective Work Plan. A complete application for assistance under ANA's Program Announcements consists of Three Parts. Part One is the SF 424, Required Government Forms, and other required documentation noted in the program announcement. Part Two of the application is a description of the project's substance. This section of the application may not exceed 45 pages. Part Three of the application is the Appendix. This section of the application may not exceed 20 pages (the exception to this 20-page limit applies only to projects that require, if relevant to the project, a Business Plan or any Third-Party Agreements). (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.*)

4. (c) *Explanation of Project Period:* Under ANA's new program announcements, project periods will be 12 months, 17 months, 24 months, or 36 months. ANA currently funds projects spanning a 36-month period. Exception: Native Language Planning Grants (Category I) will continue to be 12 or 17 month project periods. This notice clarifies the specific project periods that ANA will fund. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

4. (d) *Application Review Criteria:* ANA has expanded the review criteria to allow for a more equitable distribution of points during the application review and competition process. In the FY 2004 Program Announcement, ANA will improve the competitive review process through the use of six criteria that will evenly distribute evaluation points. The use of six criteria will standardize the review of each application and distribute the number of points more equitably. Based on the Administration for Children and

Families (ACF) Uniform Project Description, ANA's criteria categories are: Project Introduction; Objectives and Need for Assistance; Project Approach; Organizational Capacity; Results and Benefits Expected; and Budget and Budget Narrative. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 5. Program Areas of Interest

ACF supports and fosters strong families and healthy communities. In the FY 2004 Program Announcements, ANA has identified Program Areas of Interest to complement other Health and Human Services and ACF programs. For example, in ANA's SEDS program the Economic Development Areas of Interest support activities that will provide business and employment opportunities and options necessary to build the foundation of healthy communities and strong families. Under Social Development, the program areas of interest support families, elders, youth development, healthy marriage, and individuals with disabilities. Furthermore, under Governance, funding may be used for leadership and management training or to assist eligible applicants in the development of laws, regulations, codes, policies, and practices that support and promote community-based activities that lead to self-sufficiency. The program Areas of Interest are projects that ANA considers supportive to Native American communities. Although eligibility for funding is not restricted to projects of the type listed under this program announcement, these Areas of Interest are ones which ANA sees as particularly beneficial to the development of healthy Native American communities. (*Legal authority: Sections 803(a) of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b*)

### 6. Policy on Results and Benefits

ANA's program announcement will not offer an opportunity for applicants to choose from six project performance indicators. For example, indicators may be: The number of jobs created or retained; the strengthening and modification of tribal government activities such as the implementation of codes and ordinances; the number of people trained; the dollar amount of non-federal resources leveraged per grantee; the number and type of community, federal and state partnerships involved in the project; the dollar amount of private sector investments integrated into the project; and the number of community-based

small businesses established. This quantitative and qualitative data will be used to monitor grantee performance and to communicate to the public and Congress on the impact and success of locally funded ANA projects. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

*Correction:* Within the ANA Results and Benefits Criteria, a redundant performance indicator was deleted. The indicator removed was “number of families served”. The agency considered that this information was being addressed in a more comprehensive indicator: “the number of children, youth, families or elders assisted or participating”.

#### 7. ANA Funding Restrictions

ANA does not fund:

- Activities in support of litigation against the United States Government that are unallowable under OMB Circulars A-87 and A-122. (*Legal authority: Sections 803(a) and (d), and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b, and 2991b-3, 45 CFR 1336.50(a); 45 CFR 74.27 and 92.22; OMB Circular A-122, Attachment B, Paragraph 10(g) and OMB Circular A-87, Attachment B, Paragraph 14(b)*)

- Duplicative projects or does not allow any one community to receive a disproportionate share of the funds available for award. When making decisions on awards of grants the Agency will consider whether the project is essentially identical or similar, in whole or significant part, to projects in the same community previously funded or being funded under the same competition. The Agency will also consider whether the grantee is already receiving funding for a SEDs, Language, or Environmental project from ANA. The Agency will also take into account in making funding decisions whether a proposed project would require funding on an indefinite or recurring basis. This determination will be made after it is determined whether the application meets the requirements for eligibility as set forth in 45 CFR 1336, Subpart C, but before funding decisions are complete. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

*Discussion of Comment:* The writer expressed concern with the policy statement on award determination. If ANA is going to consider whether the proposed project is essentially identical or similar, in whole or in part, to

projects in the same community previously funded under the same competition, they would be competing with their consortia membership for ANA funding.

*Response:* The policy statement read in its entirety references a policy that ANA does not fund duplicative projects within the same identified community that are currently being funded or were previously funded by ANA. The intent of the policy is to not restrict consortia services to its membership and is not intended to create problematic competition within communities. It is ANA's consideration that this policy supports an internal control measure to ensure the effective use of limited federal funds by the elimination of financial awards for services and/or activities already supported by ANA. The funding restriction policy will remain intact.

*Discussion of Comment:* The writer also wanted a definition of “projects that would require funding on an indefinite or recurring basis”.

*Response:* ANA provides financial assistance for projects that are either complete or self-sustaining or funded by other than ANA funds at the end of the project period. Proposed projects that cannot demonstrate completion, or be self-sustaining or funded by other than ANA funds at the end of the proposed project period will not be considered for funding.

- Projects in which a grantee would provide training and/or technical assistance (T/TA) to other Tribes or Native American organizations that are otherwise eligible to apply. However, ANA will fund T/TA requested by a grantee for its own use or for its members' use (as in the case of a consortium), when the T/TA is necessary to carry out project objectives. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(b)(2)*)

*Discussion of Comment:* The writer expressed concerns with the statement “projects in which a grantee would provide training and/or technical assistance to other tribes or Native American organizations that are otherwise eligible to apply”.

*Response:* The policy statement read in its entirety allows for consortia to provide technical assistance in support of project objectives to its membership. The policy will remain intact.

- The purchase of real property or construction because those activities are not authorized by the Native American Programs Act of 1974, as amended. (*Legal authority: Sections 803(a) and (d)*

*and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(b)(7)*)

- Objectives or activities to support core administration activities of an organization. However, functions and activities that are clearly project related are eligible for grant funding. Under Alaska SEDS projects, ANA will consider funding core administrative capacity building projects at the village government level if the village does not have governing systems in place. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3 and 45 CFR 1336.33(b)(4)*)

- Costs associated with fund-raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions are unallowable under an ANA grant award. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.50; 45 CFR 74.27; OMB Circular A-122, Attachment B, Paragraph 23; OMB Circular A-87, Attachment B, Paragraph 21.*)

- Major renovation or alternation because those activities are not authorized under the Native American Programs Act of 1974, as amended. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- Projects originated and designed by consultants who provide a major role for themselves and are not members of the applicant organization, Tribe, or village. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- Project activities that do not further the three interrelated ANA goals of economic development, social development and governance or meet the purpose of this program announcement. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(b)(5)*)

*Correction:* The agency noted that the wording of the funding restriction “Project activities that do not further the three interrelated ANA goals of economic development, social development, governance or meet the purpose of this program announcement” should have read as “Project activities that do not further the three interrelated ANA goals of economic development or

social development or governance, or meet the purpose of this program announcement". The technical correction allows the applicant to indicate on the ANA abstract form which one of the three inter-related ANA goals is primarily being addressed.

#### 8. Administrative Policies

Applicants must comply with the following Administrative Policies:

- An applicant must provide a 20% non-federal match of the approved project costs. Applications originating from American Samoa, Guam, or the Commonwealth of the Northern Mariana Islands are covered under section 501(d) of Pub. L. 95-134, as amended (48 U.S.C. 1469a), under which HHS waives any requirement for matching funds under \$200,000 (including in-kind contributions). (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.50(b)*)

- An application from a Tribe, Alaska Native Village or Native American organization must be from the governing body. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- A non-profit organization submitting an application must submit proof of its non-profit status at the time of submission. The non-profit organization shall submit one of the following verifiable documents: (i) 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 (ii) a copy of the currently valid IRS tax exemption certificate, or (iii) a copy of the articles of incorporation bearing the seal of the State or federally-recognized Tribe in which the corporation or association is domiciled. Organizations incorporating in American Samoa are cautioned that the Samoan government relies exclusively upon IRS determination of non-profit status; therefore, articles of incorporation approved by the Samoan government do not establish non-profit status for the purpose of ANA eligibility. (*Legal Authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- If the applicant, other than a Tribe or an Alaska Native Village government, is proposing a project benefiting Native Americans or Native Alaskans, or both, it must provide assurance that its duly elected or appointed board of directors

is representative of the community to be served. To establish compliance, an applicant should provide supporting documentation and assurance that its duly elected or appointed board of directors is majority Native American. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(a)*)

- Applicants must describe how the proposed project objectives and activities relate to a locally determined strategy. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- Proposed projects must consider the maximum use of all available community-based resources. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

*Discussion of Comment:* The writer expressed concern with the statement "Proposed projects must consider the maximum use of all available community-based resources." It is interpreted by the writer that this policy will create a hardship for Native communities with limited community resources.

*Response:* This statement is intended to ensure that the applicant assesses the availability of other community resources and any opportunities and options to partner with other community-based programs. Applicants with scarce community resources will not be penalized. The policy statement will remain intact.

- Proposed projects must present a strategy to overcome the challenges that hinder movement toward self-sufficiency in the community. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- Applicants proposing an Economic Development project should address the project's viability. A business plan, if applicable, must be included to describe the project's feasibility, cash flow, and approach for the implementation and marketing of the business. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

- ANA will not accept applications from tribal components, which are tribally authorized divisions of a larger Tribe, which are not approved by the governing body of the Tribe. (*Legal authority: Sections 803(a) and (d) and*

*803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(a)*)

#### 9. DUNS Numbers

(New Requirement to receive grant awards)

On June 27, 2003, the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants, after giving notice in the **Federal Register** on June 27, 2002 and providing opportunity for public comment. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (<http://www.Grants.Gov>). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under mandatory grant programs, submitted on or after October 1, 2003. A DUNS number may be acquired at no cost by calling the dedicated toll-free DUNS number request line on 1-866-705-5711 or you may request a number on-line at <http://www.dnb.com>.

#### 10. Community and Faith-Based Organizations

The Administration for Children and Families through the Administration for Native Americans supports and fosters strong families and healthy communities under four initiatives. ANA encourages applications from eligible community and faith-based organizations that (1) provide services directly to Native American people; (2) organizations that support rural communities; (3) provide prevention and intervention programs for youth and families; and (4) promote healthy relationships to strengthen families.

#### 11. Community-Based Projects

ANA's program announcements will emphasize partnerships and community-based projects. The intent of this change is to increase the number of grants to local community organizations, to encourage new partnerships with public and private community-based organizations. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 12. Funding Thresholds

The ANA will increase funding ceilings under the Native Language program for Category I Planning and Category II Design and Implementation grants. The minimum grant amount for Native Language grants will be \$25,000. The ceiling amount for Category I grants will increase from \$60,000 to \$100,000. The ceiling amount for Category II grants will increase from \$150,000 to \$175,000. The increase in funding amounts for Native Language grants will support the effective assessment of native languages. It will also provide applicants the opportunity to incorporate new technologies necessary to design, implement, and preserve Native language and culture. Grants awarded under the Native Language program that produce audio or print media will now include a stipulation that a copy of the product be provided to ANA for the Language Repository. Federally-recognized Tribes have the option to not submit project products. The funding ceiling for Social and Economic Development Strategies (SEDS) will be reduced from \$1 million to \$500,000. The minimum grant award amount will be \$25,000. This adjustment of the minimum and maximum funding levels is due to the demand for SEDS project funding. These changes will result in additional community-based social and economic development project grant awards under the SEDS program. The Environmental Program announcement includes a suggested threshold and ceiling on proposed projects. For FY 2004 these amounts will be considered as guidelines only. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 13. Availability of Multi-Year Funding

Applicants may apply for projects of up to 36 months in duration. A multi-year project, one extending more than 12 months or 17 months, affords grantees the opportunity to undertake more complex and in-depth projects. Applicants are encouraged to develop multi-year projects. However, applicants should note that a multi-year project is a project on a single theme that requires more than 12 or 17 months to complete. It is not a series of unrelated projects presented in chronological order over a three-year period. Funding after the first budget period of a multi-year project will be non-competitive. However, multi-year funding will be contingent upon: (1) The availability of Federal funds; (2) the grantee's progress to

achieve the objectives and activities outlined in the Objective Work Plan; (3) ANA's continued belief that the project is in the public interest; and (4) the grantee is in compliance with applicable statutory and grant reporting requirements. Multi-year grant awards are subject to the availability of funds and a determination by ANA that the grantee has successfully completed its prior year objectives. Exception: Native Language Category I: Planning Grants will remain 12 or 17 month projects. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 14. Applications From Multiple Organizations in the Same Geographic Area

ANA will accept applications for funding and award grants to multiple organizations located in the same geographic area, provided the activities are not duplicative of previously funded ANA projects in the same geographic area or to the same grantee. Previously, under each competitive program area, ANA accepted one application that served or impacted a reservation, Tribe or Native American community. The reason for this change is to expand and support large Native American rural and urban communities that provide a variety of services in the same geographic area. Although Tribes are limited to three simultaneous ANA grants (one each under SEDS, Native Language and Environmental programs) at any one time, this clarification allows other community-based organizations to apply for ANA funding to support on-going community-based efforts, provided the activities do not duplicate currently funded projects serving the same geographic area. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 15. Program Specific Program Announcements

ANA's FY 2004 program announcements will now be program specific. ANA will release separate program announcements for funding opportunities under SEDS, for Language Preservation and Maintenance, Environmental Regulatory Enhancement, and for special initiatives. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 16. Policy on Training and Technical Assistance

To reduce geographic disparities, ANA's training and technical assistance curriculum and all associated handouts will be standardized. ANA's contracted training and technical assistance providers may provide training in pre-application and project development. Training will be advertised in advance, to ensure prospective applicants have the opportunity to attend. All potential ANA applicants are eligible to receive free training and technical assistance in the SEDS, Language or Environmental program areas. (*Legal authority: Sections 804 of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991c*)

### 17. Application Review Criteria

ANA has improved the competitive review process and will now use six criteria that will evenly distribute evaluation points. The use of six criteria will standardize the review of each application and distribute the number of points more equitably. ANA's criteria categories are: Project Introduction; Objectives and Need for Assistance; Project Approach; Organizational Capacity; Results and Benefits Expected; and Budget and Budget Justification. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

*Discussion of Comment:* The comments submitted by the individual suggested ANA modify its sentence structure, and increase the point weight on the budget section to emphasize its importance.

*Response:* ANA has determined that the editorial and suggested re-wording did not change the intent of the information being requested and therefore incorporated a majority of the recommended edits in the ANA evaluation criteria section of the program announcement. The ACF Uniform Project Description requires the use of specific text in program announcements and the ANA program announcement adheres to those requirements. The edits provided more clarity and cohesiveness to this section of the program announcement without changing content or intent.

*Response:* The comment to increase the point value of the ANA Budget criteria would result in a subsequent decrease in assigned point value in another criterion. ANA determined that it would not be beneficial to the overall project presentation as outlined to increase the point value for the budget section. The assignment of point values

to evaluation criteria provides the applicant with an indication as to which criteria have more merit in the overall development of an application. ANA has determined the budget criteria point value is suitable in relation to the other merit criteria and will remain as initially established.

*Technical Correction:* The ANA evaluation criteria title "Introduction and Project Summary/Abstract" was rewritten to state "Introduction and Project Summary/Project Abstract". This change was added to provide clarity and indicate to the applicant that the information requested should be indicated on the ANA Project Abstract form (OMB No. 0980-0204).

### 18. Definitions

The following definitions will be used in all ANA program announcements. In the FY 2004 Program Announcement, ANA clarifies many areas that have previously prompted numerous questions and application mistakes from applicants. The ANA program announcement will now include definitions for the following terms:

**Authorized Representative:** The person or person(s) authorized by Tribal or Organizational resolution to execute documents and other actions required by outside agencies. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Budget Period:** The interval of time into which the project period is divided for budgetary or funding purposes, and for which a grant is made. A budget period usually lasts one year in a multi-year project period. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Community:** A group of people residing in the same geographic area that can apply their own cultural and socio-economic values in implementing ANA's program objectives and goals. In discussing the applicant's community, the following information should be provided. (1) A description of the population segment within the community to be served or impacted; (2) the size of the community; (3) geographic description or location, including the boundaries of the community; (4) demographic data on the target population; and (5) the relationship of the community to any larger group or tribe. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Community Involvement:** How the community participated in the development of the proposed project, how the community will be involved during the project implementation and after the project is completed. Evidence of community involvement can include, but is not limited to, certified petitions, public meetings minutes, surveys, needs assessments, newsletters, special meetings, public Council meetings, public committee meetings, public hearings, and annual meetings with representatives from the community. The applicant should document the community's support of the proposed project. Applications from National and Regional Indian and Native organizations should clearly demonstrate a need for the project, explain how the project originated, identify the beneficiaries, and describe and relate the actual project benefits to the community and organization. National Indian and Native organizations should also identify their membership and specifically discuss how the organization operates and impacts Native American people and communities. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Completed Project:** A completed project means that the program funded by ANA is finished, self-sustaining, or funded by other than ANA funds, and the results and outcomes are achieved by the end of the project period. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Consortia—Tribal/Village:** A group of Tribes or villages that join together either for long-term purposes or for the purpose of an ANA project. Applicant must identify Consortia membership. The Consortia applicant must be the recipient of the funds. A Consortia applicant must be an "eligible entity" as defined by this program announcement and the ANA regulations. Consortia applicants should include documentation (a resolution adopted pursuant to the organization's established procedures and signed by an authorized representative) from all consortia members supporting the ANA application. An application from a consortium should 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 which duplicates activities for which member Tribes also receive funding from ANA. The consortium

application should identify the role and responsibility of each participating consortia member and a copy of the consortia legal agreement or Memoranda of Agreement to support the proposed project. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Construction:** The initial building of a facility. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Core Administration:** Salaries and other expenses for those functions that support the applicant's organization as a whole or for purposes that are unrelated to the actual management or implementation of the ANA project. However, salaries and activities that are clearly related to the ANA project are eligible for grant funding. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.33(b)(4).*)

**Economic Development:** Involves the promotion of the physical, commercial, technological, industrial, and/or agricultural capacities necessary for a sustainable local community. Economic development includes activities and actions that develop sustainable, stable, and diversified private sector local economies. For example, initiatives that support employment options, business opportunities, development and formation of a community's economic infrastructure, laws and policies that result in the creation of businesses and employment options and opportunities that provide for the foundation of healthy communities and strong families. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Equipment:** Tangible, non-expendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. However, consistent with recipient policy, lower limits may be established. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3; 45 CFR 1336.50(a); 45 CFR 74.2 and 92.3*)

**Governance:** Involves assistance to tribal and Alaska Native village government leaders to increase their ability to execute local control and



decision-making over their resources. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Implementation Plan:** The guidebook the applicant will use in meeting the results and benefits expected for the project. The Implementation Plan provides detailed descriptions of how, when, where, by whom and why activities are proposed for the project and is complemented and condensed by the Objective Work Plan. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**In-kind Contributions:** In-kind contributions are property or services which benefit a federally assisted project or program and which are contributed by the grantee, non-Federal third parties without charge to the grantee, or a cost-type contractor under the grant agreement. Any proposed in-kind match must meet the applicable requirements found in 45 CFR Parts 74 and Part 92. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Letter of Commitment:** A third party statement to document the intent to provide specific in-kind contributions or cash to support the applicant. The Letter of Commitment must state the dollar amount (if applicable), the length of time the commitment will be honored, and the conditions under which the organization will support the proposed ANA project. If a dollar amount is included, the amount must be based on market and historical rates charged and paid. The resources to be committed may be human, natural, physical, or financial, and may include other Federal and non-Federal resources. For example, a notice of award from another Federal agency committing \$200,000 in construction funding to complement a proposed ANA funded pre-construction activity is evidence of a commitment. Statements about resources which have been committed to support a proposed project made in the application without supporting documentation will be disregarded. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Leveraged Resources:** 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 completions of the project. An example would be a written letter of commitment 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. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Multi-purpose Organization:** A community-based corporation whose charter specifies that the community designates the Board of Directors and/or officers of the organization through an elective procedure and that the organization functions in several different areas of concern to the members of the local Native American community. These areas are specified in the by-laws and/or policies adopted by the organization. They may include, but need not be limited to, economic, artistic, cultural, and recreational activities, and the delivery of human services such as day care, education, and training. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Multi-year Project:** Encompasses a single theme and requires more than 12 or 17 months to complete. A multi-year project affords the applicant or opportunity to develop and address more complex and in-depth strategies that cannot be completed in one year. A multi-year project is a series of related objectives with activities presented in chronological order over a two or three-year period. Prior to funding the second or third year, of a multi-year grant, ANA will require verification and support documentation for the grantee that objectives and outcomes proposed in the preceding year were accomplished. Applicants proposing multi-year projects must complete and submit an Objective Work Plan (OWP) and budget with narrative for each project year, and fully described objectives to be accomplished, outcomes to be achieved, and the results and benefits to determine the successful outcomes of each budget period. ANA will review the quarterly and annual reports of grantees to determine if the grantee is meeting its goals, objectives and activities identified in the OWP. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs*

*Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Objective(s):** Specific outcomes or results to be achieved within the proposed project period that are specified in the Objective Work Plan. Completion of objectives must result in specific, measurable, outcomes that would benefit the community and directly contribute to the achievement of the stated community goals. Applicants should relate their proposed project objectives to outcomes that support the community's long-range goals. (*Legal authority: Section 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Partnerships:** Agreements between two or more parties that will support the development and implementation of the proposed project. Partnerships include other community-based organizations or associations, Tribes, federal and state agencies and private or non-profit organizations. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Performance Indicators:** Measurement descriptions used to identify the outcomes or results of the project. Outcomes or results must be measurable to determine that the project has achieved its desired objective and can be independently verified through monitoring and evaluation. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Real Property:** Land, including land improvements, structures, and appurtenances thereto, excluding movable machinery and equipment. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Renovation or Alteration:** The 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. Alteration and renovation may include work referred to as improvements, conversion, rehabilitation, remodeling, or modernization, but is distinguished from construction. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Resolution:** Applicants are required to include a current signed Resolution (a formal decision voted on by the official

governing body) in support of the project for the entire project period. The Resolution should indicate who is authorized to sign documents and negotiate on behalf of the Tribe or organization. The Resolution should indicate that the community was involved in the project planning process, and indicate the specific dollar amount of any non-federal matching funds (if applicable). (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Sustainable Project:** A sustainable project is an on-going program or service that can be maintained without additional ANA funds. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Self-Sufficiency:** The ability to generate resources to meet a community's needs in a sustainable manner. A community's progress toward self-sufficiency is based on its efforts to plan, organize, and direct resources in a comprehensive manner that is consistent with its established long-range goals. For a community to be self-sufficient, it must have local access to, control of, and coordination of services and programs that safeguard the health, well-being, and culture of the people that reside and work in the community. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Social Development:** Investment in human and social capital for advancing the well-being of members of the Native American community served. Social development is the action taken to support the health, education, culture, and employment options that expand an individual's capabilities and opportunities, and that promote social inclusion and combat social ills. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

### 19. Competitive Panel Review Process

ANA will consolidate the peer panel review process. ANA is required by statute to provide a peer panel review for each eligible application. Panel reviewers are selected nationally for their education, experience, and working knowledge in ANA program areas. In FY 2003, ANA began the process of expanding and rotating the pool of panel reviewers. This process will ensure that applications for funding

are reviewed, analyzed, and scored by qualified professionals in the respective program area. This organizational efficiency will ensure that each application receives appropriate consideration and that the panel review teams have the appropriate and necessary credentials to analyze, evaluate, and score applications. For example, readers with education and work experience in Environmental Regulatory Enhancement will be selected to review environmental applications. Readers with education and work experience in Language Preservation and Maintenance will be selected to review language applications. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

#### 19. (a) Initial Screening

Each application submitted under an ANA program announcement will undergo a pre-review screening to determine if (a) The application was received by the program announcement closing date; (b) the application was submitted in accordance with Application Submission Requirements; (c) the applicant is eligible for funding; (d) the applicant has submitted the proper support documentation such as proof of non-profit status, resolutions, and required government forms; and (e) an authorized representative has signed the application. An application that does not meet one of the above elements will be excluded from the competitive review process. Ineligible applicants will be notified by mail within 30 business days from the closing date of this program announcement. ANA staff cannot respond to requests for information regarding funding decisions prior to the official applicant notification. After the Commissioner has made funding decisions, unsuccessful applicants will be notified in writing within 90 days. Applicants are not ranked based on general financial need. Applicants, who are initially excluded from competition because of ineligibility, may appeal the Agency's decision. Likewise, applicants may also appeal an ANA decision that an applicants' proposed activities are ineligible for funding consideration. The appeals process is stated in the final rule published in the **Federal Register** on August 19, 1996 (61 FR 42817 and 45 CFR part 1336, subpart C). ANA has a policy of not funding duplicative projects or allowing any one community to receive a disproportionate share of the funds available for award. When making decisions on awards of grants

the Agency will consider whether the project is essentially identical or similar, in whole or significant part, to projects in the same community previously funded or being funded under the same competition. The Agency will also consider whether the grantee is already receiving funding for a SEDS project or for another project from ANA. The Agency will also take into account in making funding decisions whether a proposed project would require funding on an indefinite or recurring basis. (*Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3*)

**Correction:** Added an additional pre-screening element (f) applicants must submit a DUNS number on their SF 424 form. This element was added per the Office of Management and Budget policy published in the **Federal Register** on October 1, 2003. This section was further edited to read as follows: "An application that does not meet one of the above elements will be considered incomplete and excluded from the competitive review process. Applicants, with incomplete applications, will be notified by mail within 30 business days from the closing date of this program announcement." This amendment was inserted to clarify and make a distinction between incomplete applications, which do not have recourse to appeal, and the determination of ineligibility, which has recourse to an appeal process.

#### 19. (b) Automation of the Panel Review Process

In FY 2004, ANA will automate its application receipt and panel review process to comply with the Paperwork Reduction Act of 1995 and to support the ACF Electronic Grant Application Submission Initiative. The automation of document management will provide program operation efficiency. For example, when an application is submitted to ANA it is logged into an automated system and given an identification number. After the program announcement closing date, ANA randomly assigns each application to a peer review panel for evaluation and scoring. During the review process, panel reviewer comments are downloaded into data files. These comments are then matched and stored with the application data file. This process consolidates all applications and review information, protects the confidentiality of the panel reviewers, and allows applicants to obtain comments in a timely manner. (*Legal authority: Sections 803(a) and (d), 803C*



and 806 of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-3 and 2991d-1)

#### 19. (c) Panel Reviews and Funding Decisions

ANA values the knowledge and expertise of individual reviewers. Applications for funding are randomly assigned to panel review teams. Each panel reviewer is responsible for reading the program announcement **Federal Register** and scoring each application in accordance with the published review criteria. Each application is reviewed and scored independently by a panel reviewer. After the panel review process, ANA conducts due diligence on each application in the funding range. The ANA Commissioner determines the final action on each grant application received under ANA program announcements. The Commissioner's funding decision is based on an analysis of the application by each peer review panel, the review and recommendations of ANA staff, panel review scores, comments of State and Federal agencies having contract and grant performance related information, and other interested parties. The Commissioner makes grant awards consistent with the purpose of the Native American Programs Act (NAPA), all relevant statutory and regulatory requirements, this program announcement, and the availability of appropriated funds. (Legal authority: Sections 803(a) and (d), 803C and 806 of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b-3 and 2991d-1)

#### 19. (d) Award Notification Information

Successful applicants are notified through an official Financial Assistance Award (FAA) document. The FAA will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, the budget period, and the amount of the non-ACF matching share requirement. Unsuccessful applicants should expect notification within 90 days after the closing deadline date. (Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3)

#### 20. Web Site Information

In FY 2004, ANA may make public on its web site information associated with successfully funded applications. Such information will include the name of the grant recipient, type of award such as SEDS, Language, Environmental

amount, the duration of the project, and a synopsis of the project. Posting this information will provide prospective applicants with examples of successfully funded projects, inform the public how and where ANA is expending its funds, and share information with other HHS, ACF, federal and state agencies. The ANA website will also include profiles of successful ANA community projects, and it will provide links to other funding sources, information on special HHS, ACF and ANA initiatives, and provide an opportunity for ANA applicants to track the review and approval process of submitted applications for funding. (Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3)

#### 21. New OMB Format Requirements

The Office of Management and Budget has changed the format for program announcements published in the **Federal Register**. ANA has modified its normal program announcement format to comply with these changes.

#### Additional Information

##### Reporting Requirements

**Correction:** The Social and Economic Development Strategies program announcement included in the November **Federal Register** Notice has a typographical error in one of the references to the Reporting Requirements. The Financial Status reports (SF269) will be submitted on a quarterly basis and not semi-annually as incorrectly stated on 68 FR 64685, 64707 (November 14, 2003). Under 45 CFR 74.52(a)(1)(iii) and 45 CFR 92.41(b)(3), HHS awarding agencies are authorized to require grantees to submit Form 269s as frequently as quarterly.

Dated: February 12, 2004.

#### Quannah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 04-5043 Filed 3-5-04; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003P-0266]

#### Determination That LOVENOX (Enoxaparin Sodium) 90 Milligrams/0.6 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its determination that LOVENOX (enoxaparin sodium) 90 milligrams (mg)/0.6 milliliter (mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for enoxaparin sodium 90 mg/0.6 mL.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mueller, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval