

⁵Wyoming no longer participates in the Refugee Resettlement Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Comment on the Proposed Adoption of ANA Program; Policies and Procedures

AGENCY: Administration for Native Americans (ANA).

SUMMARY: Pursuant to section 814 of the Native American Programs Act of 1974; as amended, 42 U.S.C., 2991b-1, the Administration for Native Americans (ANA) herein describes its proposed interpretive rules, general statement of policy and rules of agency procedure or practice in relation to the Social and Economic Development Strategies (SEDS) project SMART NA Communities (Strengthening Marriages and Relationships in Tribal and Native American Communities). For FY 2005, ANA reserved an amount of funding under the SEDS program to fund projects that are beneficial to the development of healthy Native American communities. ANA has decided to participate in ACF's Healthy Marriage Initiative, and intends to use the reserved SEDS funds to support projects that improve child well-being by removing barriers associated with forming and retaining healthy families and marriages in Native American communities. 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 rule of agency procedure or practice and to give notice of the final adoption of such changes at least 30 days before the changes become effective. The notice also provides additional information about ANA's plan for administering the programs.

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

ADDRESSES: Comments in response to this notice should be addressed to Sheila Cooper, Director of Programs Operations, Administration for Native Americans, 370 L'Enfant Promenade, SW., Mail Stop: Aerospace 8—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, Aerospace Center, 901 D Street, SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Sheila Cooper, toll free at (877) 922-9262.

SUPPLEMENTARY INFORMATION: Section 814 of the Native American Programs Act of 1974 (the Act), as amended, requires ANA to provide notice of its proposed interpretive rules, statements of policy and rule of agency organization, procedure or practice. These proposed clarifications, modifications and new text will appear in the ANA FY 2005 program announcements: SEDS—SMART NA Communities.

Additional Information

1. General

This SEDS SMART NA Communities program area incorporates a majority of the requirements as contained in the SEDS program announcement. There are a few instances where ANA has opted to change the request for information for this program area only. The differences are noted below.

2. Evaluation Criteria

The Impact Indicators, as established in the FY 2005 SEDS program announcement under ANA Evaluation Criteria Five, will be used for this demonstration project except for the following: (2) Number of codes or ordinances developed and implemented; (3) number of people to successfully complete a workshop/training; (8) number of community-based small businesses established or expanded; (9) identification of Tribal or Village government business, industry, energy or financial codes or ordinances that were adopted or enacted; and (10) number of micro-businesses started. ANA does not believe that the capture of this data will affect the impact or demonstrate the success of the grants. The number of suggested ANA Impact Indicators has been reduced to five indicators. (Legal authority: Section 803(a) and (d), 803B and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b-2 and 2991b-3).

3. ANA Funding Restrictions

ANA will use the Funding Restrictions established under the FY 2005 SEDS program announcement, except for the following: Core Administration has been modified to

remove the last sentence "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." and "Projects that do not further the three interrelated ANA goals of economic development, social development and governance or meet the purpose of this program announcement." This demonstration project is not associated with the Alaska SEDS program area nor is it intended to interrelate to the goals of economic development, social development or governance. (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)

4. Administrative Policies

ANA will be using the administrative policies as included in the FY 2005 SEDS program announcement except: "An applicant can have only one active ANA SEDS grant operating at any given time" and "Applicants proposing an Economic Development project must 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." Neither of these policies apply to this program. Special initiative awards such as this program will be issued a SEDS grant number and therefore an entity will be able to administer a regular SEDS award in addition to this project. Business development and the promotion of economic development are not components of this demonstration. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, and 45 U.S.C. 2991b and 2991b-3).

5. Funding Thresholds

The funding threshold for this demonstration project will be \$50,000.00 (floor amount) to \$150,000.00 (ceiling amount) per budget period. Applications exceeding the \$150,000.00 threshold will be considered non-responsive and will not be considered for funding under this announcement. (Legal authority: Sections 803(a) and (d) and 803C of the Native American Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b-3.)

Dated: May 24, 2005.

Kimberly Romine,

Deputy Commissioner, Administration for Native Americans.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0226]

Food and Drug Administration Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 012

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 012" (Recognition List Number: 012), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of "Modifications to the List of Recognized Standards, Recognition List Number: 012" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: standards@cdrh.fda.gov. This document may also be accessed on FDA's Internet site at <http://www.fda.gov/cdrh/fedregin.html>. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 012 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 12720 Twinbrook Pkwy., MD 20857, 301-827-0021.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA will implement its standard recognition program and provided the initial list of FDA recognized consensus standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), November 15, 2000 (65 FR 69022), May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774),

October 2, 2002 (67 FR 61893), April 28, 2003 (68 FR 22391), March 8, 2004 (69 FR 10712), June 18, 2004 (69 FR 34176), and October 4, 2004 (69 FR 59240), FDA modified its initial list of FDA recognized consensus standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains "hypertext markup language" (HTML) and "portable document format" (PDF) versions of the list of FDA recognized consensus standards. Both versions are publicly accessible at the agency's Internet site at <http://www.fda.gov/cdrh/stdsprog.html>. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to Recognition List Number: 012

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA recognized consensus standards in the agency's searchable database. FDA will use the term "Recognition List Number: 012" to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 1.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
3	ASTM F1161-88, Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines	Contact person	
4	ASTM F1242-96, Standard Specification for Cuffed and Uncuffed Tracheal Tubes	Withdrawn	
7	ASTM F1627-95, Standard Specification for Pediatric Tracheostomy Tubes	Withdrawn	