draft guidance is intended to help small
entities comply with the final
regulations restricting the sale and
distribution of cigarettes and smokeless
tobacco in order to protect children and adolescents.

DATES: Although you can comment on
any guidance at any time (see 21 CFR
10.115(g)(5)), to ensure that the agency
considers your comment on this draft
guidance before it begins work on the
final version of the guidance, submit
either electronic or written comments
don the draft guidance by July 31, 2010.

ADDRESSES: The draft guidance for
industry entitled “Draft Guidance for
Industry: Compliance with Regulations
Restricting the Sale and Distribution of
Cigarettes and Smokeless Tobacco To
Protect Children and Adolescents” is
available on the Internet at http://
www.fda.gov/TobaccoProducts/
GuidanceComplianceRegulatory
Information/default.htm, or a paper
copy may be ordered free of charge by

Submit electronic comments to http://
www.regulations.gov. Submit written
comments to the Division of Dokuments
Management (HFA–305), Food and Drug
Administration, 5630 Fishers Lane, rm.
1061, Rockville, MD 20852. Identify
comments with the docket number
found in brackets in the heading of this
document.

FOR FURTHER INFORMATION CONTACT:
Kathleen K. Quinn, Center for Tobacco
Products, Food and Drug
Administration, 9200 Corporate Blvd.,
Rockville, MD 20850–3229, 240–276–1717,
Kathleen.Quinn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and
Tobacco Control Act (Tobacco Control
Act) [Public Law 111–31; 123 Stat.
1776] was enacted on June 22, 2009,
amending the Federal Food, Drug, and
Cosmetic Act (FFDCA) and providing
FDA with the authority to regulate
tobacco products. Section 102 of the
Tobacco Control Act requires FDA to
publish final regulations regarding
cigarettes and smokeless tobacco which
are identical in their provisions to the
regulations promulgated by FDA in 1996
(1996 final regulations) on August
28, 1996 (61 FR 44396), with certain
specified exceptions. In the Federal
Register of March 19, 2010 (75 FR
13225), FDA published its final
regulations entitled “Regulations
Restricting the Sale and Distribution of
Cigarettes and Smokeless Tobacco To
Tobacco To Protect Children and Adolescents. The draft guidance is being issued by the Food and Drug Administration (FDA) and is intended to help small businesses comply with the requirements of the new regulations. FDA is soliciting comments on the draft guidance document periodically as a result of comments received.

II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on “Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Public Health Support:
Division of Planning, Evaluation & Research
Native American Research Centers for Health (NARCH) V
Evidence-Based Interventions for Tribal Communities Against AIDS and STDs

Announcement Type: Competitive Supplements.
Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates
Application Deadline Date: June 30, 2010.
Review Date: July 15, 2010.
Earliest Anticipated Start Date: September 1, 2010.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive supplemental grant applications from existing Native American Research Centers for Health (NARCH) V grantees to establish and test Evidence-Based Interventions for Tribal Communities Against Acquired Immune Deficiency Syndrome (AIDS) and sexually transmitted diseases (STDs). This program is authorized under: the Snyder Act, 25 U.S.C. 13, the Public Health Service Act, 42 U.S.C. 241 as amended, and the Indian Health Care Improvement Act, 25 U.S.C. 1602(a)(b)(16). This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background
The NARCH V program supports partnerships between Federally recognized American Indian and Alaska Native (AI/AN) Tribes or Tribal organizations (including national and area Indian health boards, and Tribal colleges meeting the definition of a Tribal organization as defined by 25 U.S.C. 1603(d) or (e)) and institutions that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH). Due to the complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services (HHS) and the collaboration of academic researchers and AI/AN communities are needed to achieve significant improvements in the health status of AI/AN people. To accomplish this goal, in addition to objectives set by the Tribes, Tribal organizations or Indian health boards, the IHS NARCH program pursues the following program objectives:

To develop a cadre of AI/AN scientists and health professionals—Opportunities are needed to develop more AI/AN scientists and health professionals engaged in research, and to conduct biomedical, clinical, behavioral and health services research that is responsive to the needs of the AI/AN community and the goals of this initiative. Faculty/researchers and students at each proposed NARCH develop investigator-initiated, scientifically meritorious research projects, including pilot research projects, and will be supported through science education projects designed to increase the numbers of, and to improve the research skills of, AI/AN investigators and investigators involved with AI/ANs.

To enhance partnerships and reduce distrust of research by AI/AN communities—Recent community-based participatory research suggests that AI/AN communities can work collaboratively in partnership with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status. Community distrust of research and researchers will be reduced by offering the Tribe greater control over the research process.

Purpose
The purpose of this opportunity for supplementing the existing NARCH V program is to determine the feasibility of adapting and implementing HIV evidence based interventions (EBI)(s) supported by the CDC for effective use within AI/AN communities, and to contribute to, and document, a successful adaption and implementation.