Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 5/96, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 300, Mail Stop E–18, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, on or before August 15, 1998.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; and

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be accepted as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.(a) and 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures may be obtained in an application package. Business management technical assistance may be obtained from Sharron Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 314, Mail Stop E–18, 255 East Paces Ferry Road, NE., Atlanta, GA 30305; telephone (404) 842–6508 or the Internet at, slh3@cdc.gov. Programmatic technical assistance may be obtained from Rita Díaz-Kenney, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), Mail Stop K–10, 4770 Buford Highway NE., Atlanta, GA 30341–3724; telephone (770) 488–5016, or the Internet at: rvd1@cdc.gov.

You may also obtain this announcement, and other CDC announcements, from one of two Internet sites on the actual publication date: CDC's home-page at http://www.cdc.gov or the Government Printing Office home-page (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

Please refer to Announcement number 98082 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report; stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report; stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325; telephone (202) 512–1800.

Dated: July 9, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–18824 Filed 7–14–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ethics Subcommittee and the Advisory Committee to the Director, Centers for Disease Control and Prevention: Cancellation of Meetings

This notice announces the cancellation of previously announced meetings.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 63 FR 34901, June 26, 1998.

PREVIOUSLY ANNOUNCED TIMES AND DATES: 9 a.m.–3 p.m., July 16, 1998, and 8:30 a.m.–3 p.m. July 17, 1998.

CHANGE IN THE MEETING: These meetings have been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Linda Kay McGowan, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333, telephone 404/639–7080.

Dated: July 10, 1998.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–18934 Filed 7–14–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–98–800]

Memorandum of Understanding Between the Food and Drug Administration and the Indian Health Service

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Indian Health Service (IHS). The purpose of the MOU is to develop a more cohesive relationship to mutually address American Indian and Alaska Native issues within the context of each organization's jurisdiction.

DATES: The agreement became effective July 9, 1997.

FOR FURTHER INFORMATION CONTACT: Mary C. Wallace, Office of External Affairs (HFE–3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4406.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

BILLING CODE 4160–01–F

225-98-8000

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE FOOD AND DRUG ADMINISTRATION
AND
THE INDIAN HEALTH SERVICE

I. PURPOSE

The Food and Drug Administration (FDA) and the Indian Health Service (IHS), U.S. Department of Health and Human Services (DHHS), have mutual interests in fostering improved health care and access to policy and education programs.

FDA and IHS intend to work to develop a more cohesive relationship to mutually address American Indian and Alaska Native issues within the context of each organization's jurisdiction. FDA and IHS agree to work together to promote and support appropriate ongoing DHHS and organizationally specific initiatives, such as:

- Collaborative Tribal Consultations
  - -- National Congress of American Indians
  - -- National Indian Health Board
  - -- Regional Health Boards
- The White House Initiative on Tribal Colleges and Universities
- Expert Technical Assistance
- Collaborative Public Health Education Campaigns
  - -- Tobacco
  - -- Clinical Trials and Education
  - -- Women's Health Issues --(Urban and Rural)
  - -- "Take Time to Care" Campaign
  - -- Food Labeling Education
  - -- Food/Nutrient/Deficiency/Food supplementation issues for women of child bearing age and health professionals
  - -- Food Safety Initiative
  - -- Health Fraud
- Collaborative Consumer Studies
- Collaborative Recruitment

This MOU establishes policies and principles by which the parties may be guided when executing specific interagency agreements for the exchange of funds, services, or personnel.

II. AUTHORITY

Food and Drug Administration: Section 903 of the FFDCA (21 U.S.C. 393), Section 301 of the PHSA, (42 U.S.C. 241), Sections 1701 et seq. of the PHSA (42 U.S.C. 300u et seq.)

Indian Health Service: Transfer Act (42 U.S.C. 2001) of 1954.

III. BACKGROUND

The FDA and the IHS have been independently conducting activities, in the context of their jurisdictions, to improve the knowledge base of American Indian and Alaska Native populations and to involve these individuals in their respective processes. The FDA and the IHS recognized that the success of those efforts can be enhanced by greater collaboration.

The IHS has focused its outreach activities primarily on the needs of American Indian and Alaska Native populations. Similarly, the FDA has focused its efforts primarily upon the needs of the general population with intermittent emphasis upon American Indian and Alaska Native populations.

The goals of the FDA and the IHS collaborations will be to accomplish the following:

(1) More effectively interface with the IHS, the National Indian Health Board, the National Congress of American Indians, Regional Health Boards, and other DHHS components by:

-- soliciting tribal advice and recommendations on approaches to achieve appropriate levels of effective and efficient involvement of American Indians and Alaska Natives in the FDA's regulatory and outreach processes;

-- Enhancing local consultations and collaborations with tribal governments, when appropriate;

-- receiving assistance in improving involvement of American Indians and Alaska Natives in Agency policy initiatives;

-- discussing collaborative approaches to promote the safe and practical use of FDA-regulated products among American Indian and Alaska Native populations;

-- discussing approaches and establishing distribution systems for materials through IHS Tribal and Urban Indian Health Programs, Indian schools, community colleges and universities, IHS Medical Centers and the Department of Veterans Affairs' regional medical centers;

(2) Improve access of American Indians and Alaska Natives to FDA generated information on health risks and policy issues;

(3) provide community based organizations and concerned individuals with the opportunities to have appropriate input into regulatory processes such as;

-- encourage participation of American Indians and Alaska Natives in Agency-sponsored conferences, meetings, focus groups, and consumer studies;

-- promote opportunities to serve on the FDA's advisory committees and panels, science boards, and in research;

(4) provide FDA and IHS officials and managers with the perspectives on American Indian and Alaska Native health care and education needs and policy issues;

(5) promote diversity in the planning and application of existing educational programs and services that encourage youth to pursue careers in the sciences, math, and other disciplines that may lead to careers in the advanced sciences, engineering and the health professions; and

(6) continue recruitment efforts to American Indian and Alaska Native populations through programs such as the Cooperative Education Programs (CO-OP), Commissioned Officer Student Training and Extern Program (COSTEP), fellowships, personnel exchanges, and summer employment programs through Tribal Colleges and Universities and professional associations.

IV. SCOPE OF WORK

The FDA and the IHS hereby express their firm intentions to jointly address American Indian and Alaska Native issues within the context of regulatory processes and programs conducted by the FDA primarily for the general U.S. population, as resources permit. Given the diversity of education, knowledge, understanding and cultures within the American Indian and Alaska Native populations, the IHS will work with FDA to enhance its activities with American Indian and Alaska Native populations.

FDA and IHS have established formal liaisons for both Agencies that will foster an information exchange on all aspects of the MOU. Other functions of the Agency liaisons may include the following:

- Work with intra/inter-agency task groups to identify the type of technical assistance and outreach necessary to provide American Indian and Alaska Native populations with information and education.

- Exchange information on currently funded programs that have objectives to address the health education needs of American Indian and Alaska Native populations.

- Review opportunities for mutual and flexible funding and cooperative extension of funded programs for American Indian and Alaska Native populations through FDA and IHS grant programs.

- Strengthen mutual cooperative activities and technical support in working with other DHHS components in developing resources to collect improved statistics on American Indian and Alaska Native populations.

V. DURATION OF AGREEMENT

This MOU will become effective upon acceptance by both parties and will continue in effect indefinitely. This MOU may be modified by mutual written consent or terminated by either party upon 60 day advance notice to the other party.

VI. LIAISONS/PROJECT OFFICERS

Mary C. Wallace
Director of Consumer Programs
and FDA Minority Health Liaison
Food and Drug Administration
Office of External Affairs
Office of Consumer Affairs
5600 Fishers Lane, Room 16-85, HFE-3
Rockville, MD 20857
(301) 827-4406
Fax (301) 443-9767

Phyllis Eddy
Special Assistant to the Director
of Headquarters Operations
Indian Health Service
Office of the Director
5600 Fishers Lane, Room 6-22
Rockville, MD 20857
(301) 443-7261
Fax (301) 481-3192

/II. AUTHORIZING SIGNATURES AND DATES

APPROVED AND ACCEPTED BY
FOOD AND DRUG
ADMINISTRATION

LEAD DEPUTY COMMISSIONER
FOOD AND DRUG
ADMINISTRATION

Date: JUL - 9 1997

APPROVED AND ACCEPTED BY
INDIAN HEALTH SERVICE

DIRECTOR
INDIAN HEALTH SERVICE

Date: 07/9/97

[FR Doc. 98–18829 Filed 7–14–98; 8:45 am]
BILLING CODE 4160–01–C