proposed project for proposals in categories B and C. The samples that are sent to the investigator will be selected randomly from the domains by NCHS staff. The Director of NCHS will verify that projects have received appropriate reviews.

Requirements for the Inclusion of Women and Racial and Ethnic Minorities in Research

In NHANES III, race/ethnicity was defined by self-report as non-Hispanic white, non-Hispanic black, or Mexican American. Individuals who did not self-select into these categories were classified as ''other.'' If the proposal excludes one or more race/ethnic groups or a gender, this exclusion must be justified.

CDC is also sensitive to the stigmatization of racial/ethnic specific populations through inappropriate reporting and interpretation of findings. For all proposals that request information on race/ethnicity for the samples selected, the investigator should indicate the reason for analyzing race/ethnicity and how the results will be interpreted.

Submission of Proposals

Proposals should be submitted by October 7, 2002. All investigators who submitted letters of intent may submit proposals.

Electronic submission of proposals is encouraged. Please submit proposals to: Ms. Kika Oraegbu, National Center for Health Statistics, 6525 Belcrest Rd., Rm 1000, Hyattsville MD 20782, Phone: (301) 458–4367, FAX: (301) 458–4028, E-Mail: *KDO1@cdc.gov, Attention:* NHANES III Genetic Testing Program.

Approved Proposals

NCHS/NCEH will provide a data file with the requested recoded variables (for category B and C proposals) and a randomly assigned unique identification number that is linked to the DNA specimen. No record connecting the new number with the original identification number will be kept after the samples have been sent. These samples cannot be traced to any files maintained by NCHS. For proposals in category A, the genetic results will be sent back to NCHS so they can be linked to the NHANES III public use data in the Research Data Center for analysis.

Agency Agreement

A formal signed agreement in the form of a Materials Transfer Agreement (MTA) with individuals who have projects approved will be completed before the release of the samples. This agreement will contain the conditions for use of the DNA as stated in this document and as agreed upon by the investigators and CDC. A key component of this agreement is that no attempt will be made to link the results of the proposed research to any other data, including, but not limited to, the NHANES III public use data set. Also, the investigator agrees that the samples cannot be used for commercial purposes.

Progress Reports

A progress report will be submitted annually. CDC/NCHS IRB continuation reports are also required annually.

Disposition of Results and Samples

No DNA samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Genetics Technical Panel and the NHANES IRB. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be destroyed upon completion of the approved project. Researchers requesting DNA samples for age-race-gender studies and special studies will be required to provide NCHS with the results of all DNA tests performed for each anonymized sample. These results, once returned to NCHS, will be part of the public domain. Therefore, ample time will be given to the investigator to publish results prior to reporting the results to NCHS.

Send Request for Information: Ms. Kika Oraegbu, National Center for Health Statistics, Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1000, Hyattsville, MD 20782, Phone: 301–458–4367, FAX: 301–458–4028, E-Mail: *KDO1@cdc.gov.*

References

1. Plan and Operation of the Third National Health and Nutrition Examination Survey, 1988–94. National Center for Health Statistics. Vital Health Stat (32) 1994.

2. Clayton EW, Steinberg KK, Khoury MJ, et al. Informed consent for genetic research on stored tissue samples. JAMA 1995;274:1786–1792.

Dated: August 2, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–20038 Filed 8–7–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 02N–0332

Preparation for the International Conference on Harmonization Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH Meetings in Washington, DC, Including Progress on Implementation of the Common Technical Document'' to solicit information and receive comments on the International Conference on Harmonisation (ICH) as well as the upcoming meetings in Washington, DC. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Washington, DC, September 9 to 12, 2002, at which discussion of the Common Technical Document and the future of ICH will continue.

Date and Time: The public meeting will be held on September 5, 2002, from 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, FAX 301–827–6801, e-mail: Topperk@cder.fda.gov.

Registration and Request for Oral Presentation: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by August 29, 2002.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe,

Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 1 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by August 29, 2002, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on August 29, 2002, under Docket No. 02N–0332, at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: August 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20009 Filed 8–7–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 2002.

The National Advisory Committee on Rural Health will convene its forty-second meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health.

Date and Time: September 8, 2002, 1:30 p.m.–5 p.m.; September 9, 2002, 8:30 a.m.–4:45 p.m.; September 10, 2002, 8 a.m.–10:30 a.m.

Place: Chico Hot Springs Resort, P.O. Box 29, Pray, Montana 59047, Phone: 406–333–4933.

The meeting is open to the public.

Purpose: The National Advisory Committee on Rural Health provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health care services in rural areas.

Agenda: Sunday, September 8, at Chico Hot Springs Resort at 1:30 p.m. the chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee members. The first plenary session will consist of presentations by the Montana Quality Improvement Organization and the Montana Health Quality Network. This will be followed by reports from the Quality and Workforce Subcommittees. At 3:45 p.m. the Committee will hear a presentation from Libby Hospital and an update on the Department of Health and Human Services Rural Initiative.

Monday, September 9, at 8:30 a.m. the Committee will depart for a site visit at the Big Timber Hospital. At 11 a.m. the Committee will depart for a site visit to Livingston, Montana. Transportation to these locations will not be provided to the general public. At 3:30 p.m. the Committee will hear a presentation from a representative of the Governor's Health Workforce Study.

The final plenary session will be convened on Tuesday, September 10. Beginning at 8 a.m. there will be a review of the site visits and a report from the Quality Subcommittee. The meeting will conclude with a discussion of the Montana presentations and what issues to raise in the Committee's meeting summary that will be sent to the Secretary. The meeting will be adjourned at 10:30 a.m.

Anyone requiring information regarding the subject Committee should contact Tom Morris, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Michele Pray, Office of Rural Health Policy (ORHP), (301) 443–0835. The National Advisory Committee meeting agenda will be posted on ORHP's Web site, *http://www.ruralhealth.hrsa.gov.*

Dated: August 2, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–20040 Filed 8–7–02; 8:45 am]

BILLING CODE 4165–15–P 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the National Advisory Council for Complementary and Alternative Medicine (NACCAM).

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussion could disclose confidential