

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 wish 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.

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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.

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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