Board of Governors of the Federal Reserve System, December 12, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–32098 Filed 12–15–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee in Vital and Health Statistics (NCVHS), National Health Information Infrastructure Workgroup, Health Statistics for the 21st Century Workgroup.

Time and Date: January 11, 2001, 9 a.m.–5 p.m.

Place: Lowe's Hotel at L'Enfant Plaza, 480 L'Enfant Plaza, Washington, DC 20201, (202) 484–1000.

Status: Open.

Purpose: Two Workgroups of the NCVHS, the National Health Information Infrastructure Workgroup and the Health Statistics for the 21st Century Workgroup, are conducting a joint public hearing to solicit opinions from the public, including oral and written testimony, about the issues raised in two interim reports: ''Toward a National Health Information Infrastructure'' and ''Shaping a Vision for 21st Century Health Statistics.'' The interim reports may be downloaded from the NCVHS homepage at: *http://www.ncvhs.hhs.gov/* and all participants are encouraged to review them before the meeting.

The hearing will explore challenges to the development and implementation of a National Health Information Infrastructure (NHII). As envisioned in the interim report, the NHII is the set of technologies, standards, applications, systems, values, and laws that support all facets of individual health, health care, and public health. The broad goal of the NHII is to deliver information to individuals—consumers, patients, and professionals—when and where they need it, so they can use this information to make informed decisions about health and health care. Speakers invited by the NHII workgroup will discuss barriers to accomplishing the objectives described in the report, including financial and technical barriers to the NHII, along with recommendations for actions which could be taken to overcome constraints. Speakers will also address consumer interests and concerns and the role of principal stakeholder groups in achieving the NHII vision. The Workgroup will also hear additional testimony from the public on these areas.

The hearing will also seek comments about major trends and issues in population health and their implications for future information needs described in the report, ''Shaping a Vision for 21st Century Health Statistics.'' The report outlines themes that have emerged from national consultations involving health statistics users, public health providers, advocacy groups and health care providers at local, state, and Federal levels. The Workgroup's national consultative process has helped to identify trends and gaps in shaping the vision, as well as cross-cutting issues involved and several principles have emerged as essential qualities for developing the health statistics vision. Speakers invited by the 21st Century Workgroup will be asked to discuss specific local and state health statistics needs, specific means for generating private and public cooperation in defining health statistics needs and generating health statistics collaborations. Invited speakers will also be asked to provide specific comments and suggestions on the interim report, particularly as it relates to local and state health statistics needs and private and public cooperation.

Joint panels of speakers will address confidentiality and privacy issues pertinent to both Workgroups and will consider other topics of mutual relevance. The January hearing is the fourth and final of a series of joint public hearings conducted in several regions of the country to solicit testimony on the reports. Information from the hearings will be incorporated in the final reports expected to be completed in early 2001.

Person who would like to make a brief oral comment (3–5 minutes) during the January hearing will be placed on the agenda as time permits. To be included on the agenda, please submit testimony by January 3, 2001, to Debbie M. Jackson at (301) 458–4614, by e-mail at djackson@cdc.gov, or postal address at NCHS, Presidential Building, Room 1100, 6525 Belcrest Road, Hyattsville, Maryland 20782. Persons wishing to submit written testimony only (no more than 2–3 typewritten pages) should also adhere to the due date of January 3, 2001. Testimony will also be accepted on-site as time permits. Please consult Ms. Jackson for further information about these arrangements. Additional information about the meeting will be provided by the NCVHS homepage at: http://www.ncvhs.hhs.gov/ shortly before the meeting date.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: http://www.ncvhs.hhs.gov/.

Dated: December 11, 2000.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–32132 Filed 12–15–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grants for Education Programs in Occupational Safety and Health, Program Announcement #01001

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grants for Education Programs in Occupational Safety and Health, PA #01001, meeting.

Times and Dates: 7:30 p.m.–8 p.m., January 28, 2001 (Open); 8 p.m.–10 p.m., January 28, 2001 (Closed); 8 a.m.–6 p.m., January 29, 2001 (Closed); 8 a.m.–5 p.m., January 30, 2001 (Closed).

Place: Embassy Suites River Center, 10 E. River Center Boulevard, Covington, Kentucky 41011.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 01001.

CONTACT PERSON FOR MORE INFORMATION: Bernadine Kuchinski, Occupational Health Consultant, Office of Extramural Coordination and Special Projects,

National Institute for Occupational Safety and Health, 1600 Clifton Road, NE, Atlanta, Georgia 30333. Phone 404/639–3342, e-mail bbk1@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 11, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–32102 Filed 12–15–00; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1631]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance document for industry (No. 116) entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23). This draft guidance document has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the genotoxicity of veterinary drug residues in human food in the European Union, Japan, and the United States.

DATES: Submit written comments on the draft guidance document by January 17, 2001, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance document entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/fda/TOCs/guideline.html. Persons without Internet access may submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

You may submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the VICH: Sharon Thompson, Center for Veterinary Medicine, (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e–mail: sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6524, e-mail: candres1@cvm.fda.gov.

Regarding the draft guidance document: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/ New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Genotoxicity Studies

The VICH Steering Committee held a meeting on June 14 through 16, 2000, and agreed that the draft guidance document entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies'' (VICH GL23) should be made available for public comment. This draft guidance document has been adapted for veterinary use by the VICH from guidances regarding pharmaceuticals for human use which were adopted by the ICH and published in the **Federal Register** of April 24, 1996 (61 FR 18197), and November 21, 1997 (62 FR 62471). This draft guidance document is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory