

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 02N-0308]

**Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and "Lookback" Requirements**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and 'Lookback' Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 8, 2002 (67 FR 62727), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0116. The approval expires on November 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: December 26, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 02-33139 Filed 12-31-02; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 02N-0518]

**Preparation for International Conference on Harmonisation Meetings in Tokyo, Japan, Including Progress on Implementation of the Common Technical Document and Update on New Topics**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration is announcing the following meeting: "Preparation for ICH Meetings in Tokyo, Japan, February 3 through 6, 2003. Including Progress on Implementation of the Common Technical Document (CTD) and Update on New Topics" to solicit information and receive comments on the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) as well as the upcoming meetings in Tokyo, Japan. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tokyo, Japan, February 2003, at which discussion of the CTD and the future of ICH will continue.

*Date and Time:* The meeting will be held on January 21, 2003, from 10:30 a.m. to 2 p.m. Submit registration material by January 14, 2003.

*Location:* The meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20875.

*Contact Person:* Kimberly L. Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, FAX 301-827-6801, e-mail: [Topperk@cder.fda.gov](mailto:Topperk@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:** The ICH 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. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, 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 (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and representatives of the observers: WHO, Health Canada 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 at the following Web site: <http://www.ich.org>.

*Registration and Requests for Oral Presentations:* 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 January 14, 2003.

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 January 14, 2003, 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.

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

**Agenda:** The agenda for the public meeting will be made available on January 14, 2003, at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under docket number 02N-0518.

**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: December 26, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 02-33075 Filed 12-31-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Health Professions and Nurse Education Special Emphasis Panel; Notice of Partially Closed Meetings

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 following Health Professions and Nurse Education Special Emphasis Panel meetings by teleconference. The meetings will be partially closed to the public. The public can join the open session of the meetings in person at the address listed below. The closed session of the meetings is in accordance with the provision set forth in section 552(b)(c)(6), Title 5 U.S.C., and the Determination by the Associate Administrator for Management and Program Support, Health Resources and Services Administration, pursuant to Pub. L. 92-463.

**Name:** Field Experience in Public Health Nursing in State and Local Health Departments for Baccalaureate Nursing Students (Section 831 D52).

**Date and Time:** January 6-10, 2003.; January 13-15, 2003.

**Place:** DHHS, Parklawn Building, 5600 Fishers Lane, Room 11A-33, Rockville, MD 20857.

**Open on:** January 6, 2003, 12 p.m. to 1 p.m.

**Closed on:** January 6-10, 2003, 1 p.m. to 6 p.m.; January 13-15, 2003, 1 p.m. to 6 p.m.

**Name:** Basic Nurse Education and Practice: Geriatric Nursing Knowledge and

Experiences in Long Term Care Facilities for Nursing Students (Section 831 D53).

**Date and Time:** January 6-8, 2003.

**Place:** DHHS, Parklawn Building, 5600 Fishers Lane, Room 11A-33, Rockville, MD 20857.

**Open on:** January 6, 2003, 11 a.m. to 12 p.m.

**Closed on:** January 6, 2003, 12 a.m. to 6 p.m.; January 7-8, 2003, 12 p.m. to 6 p.m.

**Purpose:** The Health Professions and Nurse Education Special Emphasis Panel shall advise the Associate Administrator for Health Professions on the technical merit of grants to improve the training, distribution, utilization, and quality of personnel required to staff the Nation's health care delivery system.

**Agenda:** The open portion of each meeting will cover introductions, opening remarks, housekeeping details, and an orientation to the review process. The closed portion of each meeting will involve the review, discussion, and evaluation of grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**For Further Information Contact:** Anyone wishing to obtain a roster of members or other relevant information should write or contact Ms. Wilma Johnson, Acting Director, Office of Peer Review, Bureau of Health Professions, Parklawn Building, Room 11A-33, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-6339.

Dated: December 26, 2002.

**Jon L. Nelson,**

*Associate Administrator for Management and Program Support.*

[FR Doc. 02-33078 Filed 12-31-02; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice of Availability. Final Restoration Plan and Environmental Assessment

**AGENCY:** U.S. Fish and Wildlife Service, U.S. Department of the Interior.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Fish & Wildlife Service (Service), on behalf of the U.S. Department of the Interior (DOI), as a Natural Resource Trustee (Trustee), announces the release of the Final Restoration Plan and Environmental Assessment (RP/EA) for the Charles George Land Reclamation Trust Superfund Site in Tyngsborough, Massachusetts. The Final RP/EA describes the Trustees' selected action to restore natural resources injured as a result of chemical contamination at the Charles George Landfill.

**ADDRESSES:** Requests for copies of the Final RP/EA may be made to: Laura Eaton-Poole, U.S. Fish and Wildlife Service, New England Field Office c/o

Great Meadows National Wildlife Refuge, Weir Hill Road, Sudbury, Massachusetts 01776. Copies are also available on the Internet at: <http://greatmeadows.fws.gov/charlesgeorge.html>.

#### FOR FURTHER INFORMATION CONTACT:

Laura Eaton-Poole, U.S. Fish and Wildlife Service, New England Field Office c/o Great Meadows National Wildlife Refuge, Weir Hill Road, Sudbury, Massachusetts 01776. Interested parties may also call 978-443-4661, extension 17, or send e-mail to [Laura\\_Eaton@fws.gov](mailto:Laura_Eaton@fws.gov) for further information.

**SUPPLEMENTARY INFORMATION:** Under the authority of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 as amended, commonly known as Superfund, (42 U.S.C. 9601 *et seq.*). “\* \* \* [Trustees] may assess damages to natural resources resulting from a discharge of oil or a release of a hazardous substance \* \* \* and may seek to recover those damages.” Natural resource damage assessments are separate from the cleanup actions undertaken at a hazardous waste site, and provide a process whereby the Trustees can determine the proper compensation to the public for injury to natural resources.

Three natural resource trustees settled with the Potentially Responsible Parties for injuries to natural resources due to releases of hazardous substances from the Charles George Landfill Superfund Site: DOI recovered \$299,916 for injuries to migratory birds that use wetlands; National Oceanic Atmospheric Administration recovered \$134,624 for potential injuries to anadromous and catadromous fish in the Merrimack River; and the Commonwealth of Massachusetts recovered \$918,900 for injuries to wetlands and groundwater. The total recovery of damages and future oversight expenses for all the Trustees was \$1,353,440. The three Trustees signed a memorandum of Agreement (MOA) in recognition of the common interests to restore, replace and/or acquire the equivalent natural resources which were injured, destroyed, or lost by the releases of hazardous substances. The MOA provides a framework for the development of a Trustee Council that cooperatively develops and implements a Restoration Plan.

The Final RP/EA is being released in accordance with Section 111(i) of CERCLA, 42 U.S.C. 9611(i) and the National Environmental Policy Act (NEPA). The Final RP/EA describes a