

groups will be on the available clinical data from both randomized clinical trials and other studies of the efficacy of opioid analgesics, and comparison of that data to the data from studies of non-opioid analgesics used in the treatment of CNCP.

Date and Time: The public workshop will be held on May 30, 2012, from 1 p.m. to 5:15 p.m. and on May 31, 2012, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Natcher Auditorium, Natcher Conference Center, National Institutes of Health Campus, 45 Center Dr., Bethesda, MD 20892.

Contacts: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6178, Silver Spring, MD 20993-0002, (301) 796-3519; or Matthew Sullivan, Center for Drug Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3160, Silver Spring, MD 20993-0002, (301) 796-1245.

Registration: If you wish to attend the workshop or provide oral comments during the open session of the meeting, please email your registration to CDER_ChronicPain_Workshop@FDA.HHS.GOV by May 15, 2012. Those without email access may register by contacting one of the persons listed in the *Contacts* section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

Registration is free and will be on a first-come, first-served basis. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing the meeting registration for the workshop at: <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>.

An open session of the meeting will be held between 3:45 p.m. and 5 p.m. on May 30, 2012, during which time public comments will be accepted. We will try to accommodate all persons who wish to speak at this open session; however, the duration of each speaker's testimony may be limited by time constraints.

Comments: Submit either electronic or written comments by August 1, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket

number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you need special accommodations due to a disability, contact Mary Gross or Matthew Sullivan (see *Contacts*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Introduction

CNCP is a major cause of pain and disability for millions of Americans. The prescribing of opioids for pain has risen steadily in the United States over the past two decades, including the prescribing of opioids to treat CNCP. Questions have been raised about the efficacy of opioids in the treatment of CNCP, including which patients benefit from the chronic use of opioids, the durability of analgesia provided by opioid analgesics, and how best to manage the use of these drugs.

Addressing this uncertainty begins with a discussion of the available scientific data on the use of opioids in chronic painful conditions. The discussion will include health care professionals, clinical investigators, regulators, manufacturers, patients, caregivers, and advocacy groups. Where gaps in our knowledge are identified, it will be important to discuss the research that needs to be undertaken to better understand the effectiveness of all analgesics for the treatment of chronic non-cancer pain, and opioid analgesics in particular.

The purpose of the meeting is to provide a forum to discuss the available data on the use of analgesics in the treatment of CNCP, beginning with a discussion of the underlying mechanisms of chronic pain and the epidemiology of chronic pain in the United States. Next, data on the efficacy of opioids and other analgesics in the treatment of chronic pain from a variety of sources will be reviewed. Those sources will include randomized controlled trials, epidemiological studies, case series and other types of studies. Patient and clinician perspectives on the pharmaceutical treatment of CNCP will be presented by people living with chronic pain and those who treat or care for patients with chronic pain. Finally, a general assessment of the available data and discussion of future research needs and next steps will be used to inform future actions that can help guide appropriate therapy for patients with CNCP.

FDA will be considering the following questions during the workshop:

1. What is currently known about the mechanisms of chronic pain?

2. How might this knowledge affect the use of pharmaceuticals chronically for the treatment of pain?

3. What is known regarding use of pain biomarkers (e.g., phenotyping, imaging, genotyping)?

4. What is known about the sources of chronic pain, the populations affected by it, and trends in current use of pharmaceuticals in its treatment?

5. What data are available from controlled trials that have examined the use of pharmaceuticals in the treatment of chronic pain?

6. What data are available from other sources on the use of pharmaceuticals in the treatment of chronic pain?

7. Can populations and individuals who would benefit from chronic use of pharmaceuticals be identified?

8. Can individuals at high risk for adverse effects be identified?

9. What more should be known about the use of pharmaceuticals to treat chronic pain?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at <http://www.regulations.gov> and may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 2, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-2757 Filed 2-7-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act, 42

U.S.C. 4321–4347, the National Institutes of Health (NIH) is issuing this notice to advise the public that an environmental impact statement will be prepared for the National Institutes of Health, Bethesda Campus Master Plan, Bethesda, Maryland.

DATES: The Scoping Meeting is planned for 6 p.m. on February 28th, 2012. Scoping comments must be postmarked no later than March 26, 2012 to ensure they are considered.

ADDRESSES: The Scoping Meeting will be held at 6001 Executive Plaza, Conference Room D, Bethesda, Maryland. All comments and questions on the Scoping Meeting and Environmental Impact Statement should be directed to Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone (301) 496–7775; fax (301) 480–8056; or email nihnepa@mail.nih.gov.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone (301) 496–7775; fax (301) 480–8056; or email nihnepa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: NIH is the focal point of the federal government for health research and is one of the world's foremost biomedical research institutions. The NIH mission is to discover new knowledge that will lead to better health for all. To achieve that mission, nearly eighty percent of the total NIH budget is expended in the form of peer-reviewed, competitively awarded research grants, cooperative agreements, and contracts to nearly 50,000 principal investigators at more than 1,700 institutions across the country including universities, medical schools, and hospitals. In addition, some 2,000 research projects are conducted in the NIH intramural laboratories and at the NIH Clinical Center. Research is conducted at both the basic and clinical levels, encompassing studies related to the prevention, diagnosis, treatment and cure of the many diseases that afflict the men, women and children of the world. In addition, the basic research supported by NIH provides the foundation for the nation's pharmaceutical and biotechnology industries. As one measure of the agency's excellence in research, it should be noted that NIH-supported

investigators won over 107 Nobel Prizes from 1939 to 2002.

A Master Plan is an integrated series of documents that present in graphic, narrative, and tabular form the current composition of NIH campuses and the plan for their orderly and comprehensive development over a 20-year period. The plan provides guidance in coordinating the physical development of NIH campuses, including building locations, utility capacities, road alignments, parking facilities, and the treatment of open spaces. General design guidelines are also used to provide detailed guidance for the placement and design of physical improvements.

The proposed action is to develop a long-range physical master plan for NIH. The plan will cover a 20-year planning period and address the future development of the NIH site, including placement of future construction; vehicular and pedestrian circulation; parking within the property boundaries; open space in and around the campus; required setbacks; historic properties; natural and scenic resources; noise; and lighting. The plan will examine potential growth in NIH personnel and consequent construction of space over the planning period. Future construction on the site could include such facilities as new animal holding, research laboratories, and support facilities.

In accordance with 40 CFR 1500–1508 and DHHS environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed master plan. The EIS will evaluate the impacts of the master plan should development occur as proposed. Among the items the EIS will examine are the implications of the master plan on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services. To ensure that the public is afforded the greatest opportunity to participate in the planning and environmental review process, NIH is inviting oral and written comments on the master plan and related environmental issues.

The NIH will be sponsoring a public Scoping Meeting to provide individuals an opportunity to share their ideas on the master planning effort, including recommended alternatives and environmental issues the EIS should consider. All interested parties are encouraged to attend. NIH has established a 45-day public comment period for the scoping process.

Dated: February 2, 2012.

Daniel G. Wheeland,
*Director, Office of Research Facilities
Development and Operations, National
Institutes of Health.*

[FR Doc. 2012–2921 Filed 2–7–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following 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 the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences, Special Emphasis Panel, Environmental Stem Cells Research.

Date: February 29–March 2, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Hotel, 150 Park Drive, Ballroom ABC, Research Triangle Park, NC 27709.

Contact Person: Teresa Nesbitt, Ph.D., DVM, Chief, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–7571, nesbitt@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 31, 2012.

Jennifer S. Spaeth,
*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. 2012–2871 Filed 2–7–12; 8:45 am]

BILLING CODE 4140–01–P