

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Officer [Signature]

[Docket No. 2004N-0559]

Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 16, 2005, from 8 a.m. to 6 p.m., and on February 17 and 18, 2005, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2004N-0559—Overall Benefit to Risk Considerations for COX-2 Selective Nonsteroidal Anti-inflammatory Drugs and Related Agents" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. ~~All comments received will be posted without change, including~~
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per
Linda
Sherman
(OC)
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2005-4090

~~any personal information provided.~~ Comments received by February 4, 2005, will be provided to the committee before the meeting.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper or Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6801, e-mail: topperk@cder.fda.gov or spelllesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512532 or 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will discuss the overall benefit to risk considerations (including cardiovascular and gastrointestinal safety concerns) for COX-2 selective nonsteroidal anti-inflammatory drugs and related agents. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the headings "Arthritis Advisory Committee" or "Drug Safety and Risk Management Advisory Committee" (click on the year 2005 and scroll down to the above named committee meetings).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the Division of Dockets Management (see *Addresses*). Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on February 17, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations

should notify the contact person before February 4, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

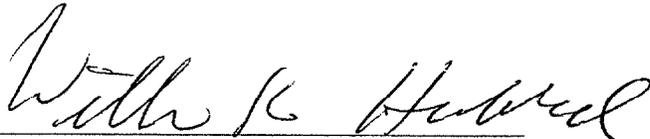
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tony Slater at 301-827-7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act

(5 U.S.C. app. 2).

Dated: January 11, 2005
January 11, 2005.



William K. Hubbard,
Associate Commissioner for Policy and Planning.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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