

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB
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Certifier N. Hawkins

Nonprescription Drugs 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 Committee: Nonprescription Drugs Advisory Committee with members from the following committees: Anesthetic and Life Support Drugs Advisory Committee, Arthritis Advisory Committee, Cardiovascular and Renal Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee, and Gastrointestinal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on September 19 and 20, 2002, from 8 a.m. to 5 p.m.

Location: Hilton, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Sandra Titus or LaNise Giles, 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, or e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code

12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 19, 2002, the committee will discuss safety issues related to the use of acetaminophen. The primary area for discussion will focus on potential hepatotoxicity related to the use of acetaminophen in both over-the-counter (OTC) and prescription (RX) products. On September 20, 2002, the committee will discuss safety issues related to the use of aspirin and other OTC nonsteroidal anti-inflammatory drugs (NSAIDS). The primary areas for discussion will focus on potential gastrointestinal bleeding and renal insufficiency related to the use of these products.

In rulemaking, the agency has proposed aspirin and acetaminophen as category I ingredients for safety and effectiveness. Other NSAIDS and combination products are marketed under new drug applications. The agency continues to believe that these ingredients are safe and effective in the prescription and OTC products currently on the market when properly used. The advisory committee will discuss whether labeling or other measures are warranted to reduce the risk of occurrence or the severity of these adverse reactions.

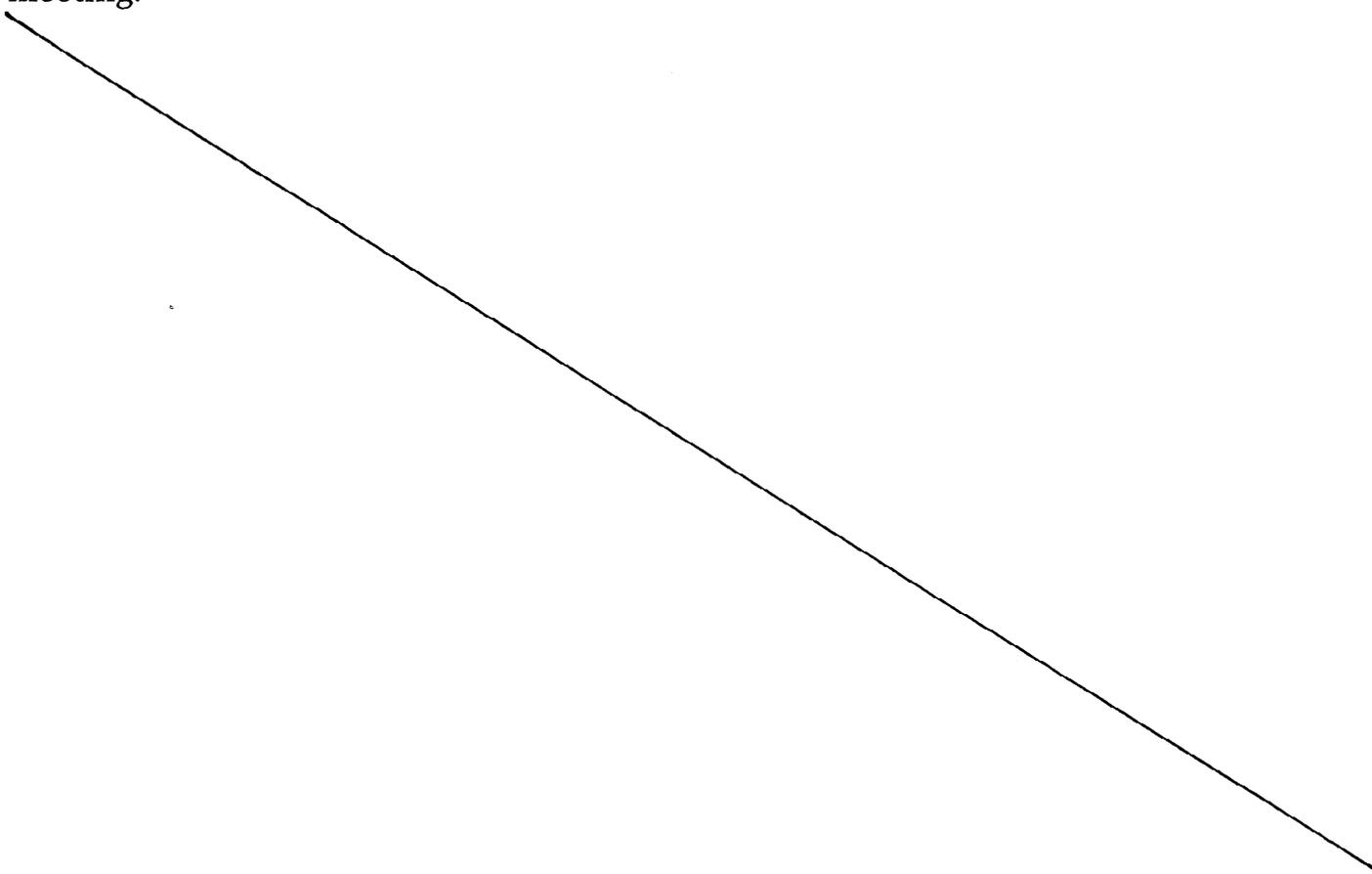
Background material will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. Click on the year 2002 and go to the September 19th and 20th Nonprescription Drugs Advisory Committee file. As background material becomes available from FDA and interested parties, it will be posted.

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 contact person by August 26, 2002. Submissions received by this date will be distributed to the committee as well

as posted on the docket site for this meeting. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2002, 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.

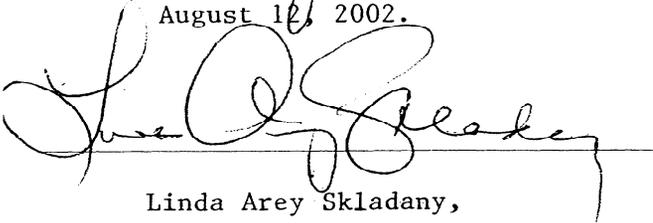
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.



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

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

Dated: August 12, 2002
August 12, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Lawn P. Hawkins