

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Food and Drug Administration

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Certifier D. Hawkins

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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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:* Arthritis 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 March 4, 2003, from 9 a.m. to 4 p.m. and on March 5, 2003, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Contact Person:* Kathleen Reedy 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, fax: 301-827-6776, e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On March 4, 2003, the committee will hear a safety update on tnf alpha inhibitors; Humira (adalimumab), Abbott Laboratories; REMICADE

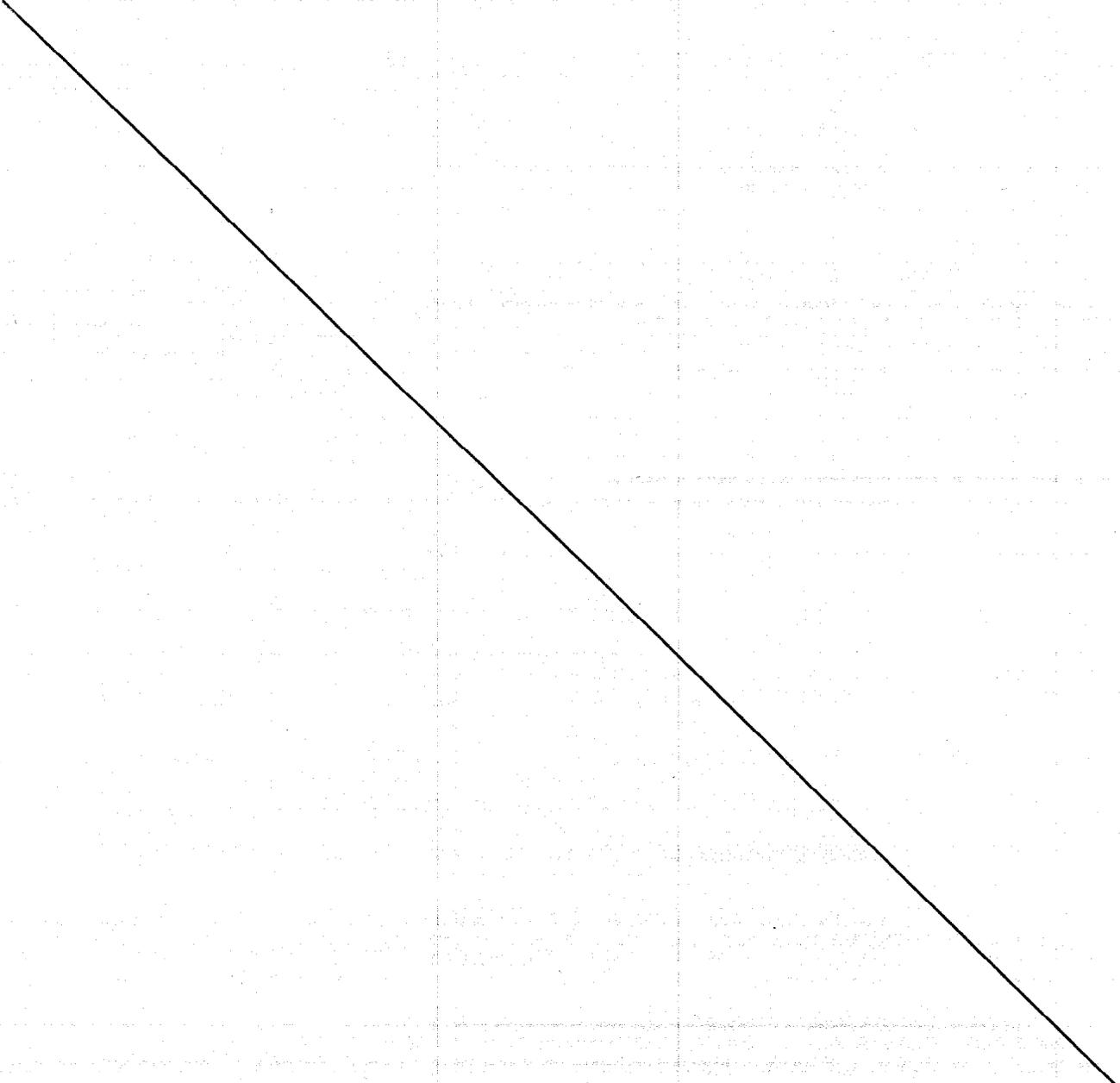
(infliximad), Centocor; and ENBREL (etanercept), Immunex. On March 5, 2003, the committee will discuss the approved product new drug application (NDA) 20-905, ARAVA, (leflunomide), Aventis Pharmaceuticals, Inc., clinical data regarding efficacy for improvement in physical function in rheumatoid arthritis, as well as a safety update. The background material for this meeting will be posted on the Internet when available or 1-working day before the meeting at: [www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm).

*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 February 25, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 4, 2003, and between approximately 8:30 a.m. and 9 a.m. and 11:30 a.m. and 12 noon on March 5, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2003, 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 LaNise Giles at 301-827-7001 at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 2003, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

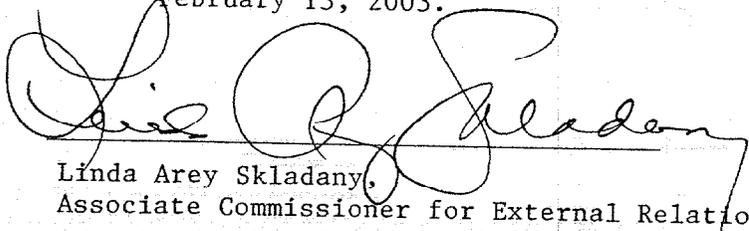


Notice of this meeting is given under the Federal Advisory Committee Act

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

Dated: Feb 13, 2003

February 13, 2003.



Linda Arey Skladany,  
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Dawn P. Hawkins