DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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: 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 September 6, 2005, from 8:30 a.m. to 4:30 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Johanna M. Clifford, 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: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologics license application (BLA) 125118/0, proposed trade name ORENCIA (abatacept), Bristol Myers Squibb, proposed indication for the treatment of moderately to severely active rheumatoid arthritis. When available, background materials for this meeting will be posted 1 business day before the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Arthritis Advisory Committee.)

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, 2005. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 26, 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 Johanna Clifford 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: July 20, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–14751 Filed 7–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 8 and 9, 2005, from 8 a.m. to 5 p.m.

Location: Holiday Inn Washington Silver Spring, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301–589–0800.

Contact Person: Cathy Groupe, 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, e-mail: *groupec@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted one business day prior to the meeting on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Endocrinologic and Metabolic Drugs Advisory Committee.)

Agenda: On September 8, 2005, the committee will discuss new drug application (NDA) 21–868, proposed trade name EXUBERA (insulin recombinant deoxyribonucleic acid (rDNA) origin powder for oral inhalation), 1 milligram (mg) and 3 mg powder for inhalation, Pfizer, Inc., for the treatment of adult patients with diabetes mellitus. On September 9, 2005, the committee will discuss NDA 21–865, proposed trade name PARAGLUVA (muraglitazar) Tablets, 2.5 mg and 5 mg, Bristol-Myers Squibb, for the treatment of type II diabetes mellitus.

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 31, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 August 31, 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 John Lauttman at least 7 days in advance of the meeting at 301–827–7001.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).