that LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. To date, GSK has not marketed LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg. In previous instances (see, e.g., 67 FR 79640, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The petitioner identified no data or other information suggesting that LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were withdrawn from sale as a result of safety or effectiveness concerns. GSK has marketed other strengths of LAMICTAL (lamotrigine) tablets: 25 mg, 100 mg, 150 mg, and 200 mg. FDA has reviewed its files for records concerning the withdrawal of LAMICTAL (Lamotrigine) tablets, 50 mg and 250 mg. There is no indication that GSK's decision not to market LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, commercially is a function of safety or effectiveness concerns, and no information has been submitted to the docket concerning the reason for which LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were withdrawn from sale. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety and effectiveness. ANDAs that refer to LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, may be approved by the agency, as long as they meet all relevant legal and regulatory requirements for approval of ANDAs.

Dated: February 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3713 Filed 3–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anti-Infective Drugs Advisory Committee and the Pediatric 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: Anti-Infective Drugs Advisory Committee and the Pediatric 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 April 12, 2007, from 8:30 a.m. to 5 p.m.

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

Contact Person: Sohail Mosaddegh, 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: *sohail.mosaddegh@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), codes 3014512530 or 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss clinical trial designs for products that seek indications for the prevention and/or treatment of disease caused by Shiga toxin-producing bacteria. FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

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 on or before March 29, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before March 21, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 22, 2007.

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 Sohail Mosaddegh 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: February 26, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–3720 Filed 3–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0055]

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 April 12, 2007, from 8:30 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select ''2007N–0055—Arcoxia—Arthritis Advisory Committee Meeting, April 12, 2007'' 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, by close of business on March 29, 2007. All comments will be posted without change, including any personal information provided. Comments received on or before March 29, 2007, will be provided to the committee before the meeting.

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

Contact Person: Johanna 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: *Johanna.Clifford@fda.hhs.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 new drug application (NDA) 21–389/21–772, ARCOXIA (etoricoxib), Merck & Co., Inc., proposed treatment for the relief of signs and symptoms of osteoarthritis.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

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 on or before March 29, 2007. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before March 21, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 22, 2007.

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 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: February 26, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–3722 Filed 3–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal 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: Cardiovascular and Renal 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 April 18, 2007, from 8 a.m. to 5 p.m.

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

Contact Person: Cathy A. 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, FAX: 301–827–6776, e-mail: *Cathy.Groupe@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the information line for up-to-date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 20–758/S–037, AVALIDE (irbesartan plus hydrochlorothiazide), Bristol-Myers Squibb Co. The sponsor is seeking approval for first-line use in hypertensive patients unlikely to achieve blood pressure goals on one drug. The committee will be asked to consider what constitutes adequate data to support such a claim and how the information can be most usefully displayed in labeling.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

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 on or before April 3, 2007. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of