Place: John M. Eisenberg Building, AHRQ Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: February 20, 2007.

Carolyn M. Clancy,

Director.

[FR Doc. 07–978 Filed 3–2–07; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for ''Consumer Assessment of Healthcare Providers and Systems (CAHPS)'' are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: Consumer Assessment of Healthcare Providers and Systems (CAHPS).

Date: March 20, 2007 (Open on March 20 from 9 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

Place: John M. Eisenberg Building, AHRQ Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: February 20, 2007.

Carolyn M. Clancy,

Director.

[FR Doc. 07–979 Filed 3–2–07; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0237]

Determination That LAMICTAL (Lamotrigine) Tablets, 50 Milligrams and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that LAMICTAL (lamotrigine) tablets, 50 milligrams (mg) and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for lamotrigine tablets, 50 mg and 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, are the subject of approved NDA 20–241 held by GlaxoSmithKline (GSK). LAMICTAL (lamotrigine) is an antiepileptic drug indicated as adjunctive therapy for partial seizures in adults and pediatric patients. It is also approved for conversion to monotherapy in adults with partial seizures who are receiving treatment with a single enzyme-inducing antiepileptic drug or valproate. In addition, LAMICTAL (lamotrigine) is indicated for the maintenance treatment of Bipolar I Disorder in certain patients.

FDA approved the NDA for LAMICTAL (lamotrigine) tablets, including the 50 mg and 250 mg strengths, on December 27, 1994. GSK has never marketed the 50 mg and 250 mg strengths of LAMICTAL (lamotrigine) tablets.

In a citizen petition dated June 9, 2005 (Docket No. 2005P–0237/CP1), submitted under 21 CFR 10.30, J. Mark Pohl of Pharmaceutical Patent Attorneys, LLC, requested that the agency determine whether LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined

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.