

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]

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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).

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Determination That LAMICTAL (Lamotrigine) Tablets, 50 Milligrams and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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