

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P-0237]

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Certifier D. Hawkins

Determination That LAMICTAL (Lamotrigine) Tablets, 50 Milligrams and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA) has determined that LAMICTAL (lamotrigine) tablets, 50 milligrams (mg) and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness.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

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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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).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.

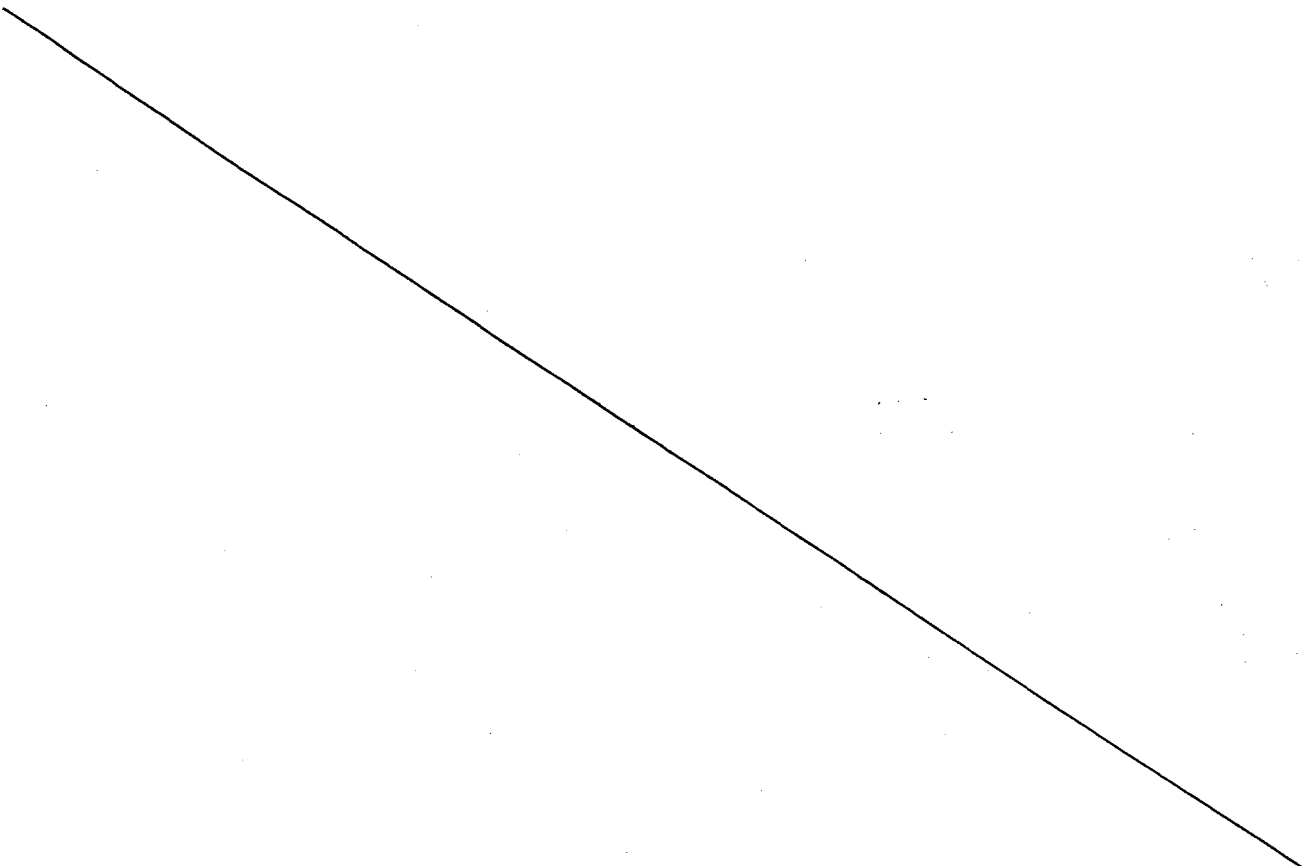
FDA approved the NDA for LAMICTAL (lamotrigine) tablets, including the 50 mg and 250 mg strengths, on December 27, 1994. GSK has never marketed the 50 mg and 250 mg strengths of LAMICTAL (lamotrigine) tablets.

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

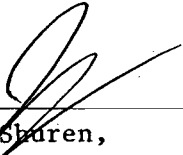
uncovered nothing that would indicate that LAMICTAL (lamotrigine) tablets, 50 mg and 250 mg, were withdrawn from sale for reasons of safety or effectiveness.

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: 2/26/07
February 26, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins