

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P-0372]

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Certifier D. Hawkins

Determination That MEPRON (Atovaquone) Tablets, 250 milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that MEPRON (atovaquone) tablets, 250 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 atovaquone tablets, 250 mg.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, 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 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).

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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 (the 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.161(a)(1) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

MEPRON (atovaquone) tablets, 250 mg, are the subject of approved NDA 20–259 held by GlaxoSmithKline (Glaxo). MEPRON (atovaquone) tablets, 250 mg, approved November 25, 1992, are indicated for the prevention of *Pneumocystis carinii* pneumonia in patients who are intolerant to trimethoprim-sulfamethoxazole (TMP-SMX). Glaxo ceased marketing MEPRON (atovaquone) tablets, 250 mg, in 1995.

Lachman Consultant Services, Inc., submitted a citizen petition dated September 7, 2006 (Docket No. 2006P–0372/CP1), under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether MEPRON (atovaquone) tablets, 250 mg, were withdrawn from sale for reasons of safety or effectiveness. The agency has determined that Glaxo’s MEPRON

(atovaquone) tablets, 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MEPRON tablets, 250 mg, were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, Glaxo's MEPRON (atovaquone) tablets, 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list MEPRON (atovaquone) tablets, 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 or effectiveness. ANDAs that refer to MEPRON (atovaquone) tablets, 250 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs.

Dated: 5/10/07
May 10, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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Dawn P. Hawkins