DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 2006P–0372]

Determination That MEPRON (Atovaquone) Tablets, 250 milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that MEPRON (atovaquone) tablets, 250 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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). 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.161(a)(1) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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


Jeffrey Shuren, Assistant Commissioner for Policy.

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I. Background
FDA is announcing the availability of a guidance for industry entitled “Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.” FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA’s Oncologic Drugs Advisory Committee. This guidance provides background information and general principles. The endpoints discussed in this guidance are for drugs to treat patients with an existing cancer. This guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

The availability of a draft of this guidance was announced in the Federal Register of April 4, 2005 (70 FR 17095). Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration by FDA in finalizing this guidance, and some of the changes are summarized here. The section on future methods for assessing progression has been clarified based on the comments received and FDA’s current thinking and practice. The section on no treatment or placebo control and the section on isolating drug effect in combination also have been clarified based on the comments received and FDA’s view that these do not directly concern the selection or evaluation of endpoints. Throughout the guidance document, the language has been condensed and simplified to be concise and clear.

II. The Paperwork Reduction Act of 1995
This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014; the collections of information in 21 CFR part 314 have been approved under 0910–0001, and the collections of information referred to in the guidance for industry entitled “Special Protocol Assessment” have been approved under 0910–0470.

III. Comments
Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access