OMB control number 0910–0599. The approval expires on May 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9436 Filed 5–15–07; 8:45 am]

BILLING CODE 4160–01–S

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Determination That MEPRON (Atovaquone) Tablets, 250 milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that MEPRON (atovaquone) tablets, 250 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the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 oreffectiveness. 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: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9348 Filed 5–15–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0112]

Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.'' This guidance provides recommendations to applicants on endpoints for cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications, biologics license applications, or supplemental applications. Applicants are encouraged to use this guidance to design cancer clinical trials and to discuss protocols with the agency. This guidance provides background information and discusses general regulatory principles. Additional companion guidances will follow and will focus on endpoints for specific cancer types (e.g., lung cancer, colon cancer) to support drug approval or labeling claims. This guidance, and the subsequent indication-specific guidances, should speed the development and improve the quality of protocols submitted to the agency to support anticancer effectiveness claims.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and