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Determination That MEPRON (Atovaquone) Tablets, 250 milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that MEPRON (atovaquone) tablets, 250 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the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

BILLING CODE 4160–01–S

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

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Rajeshwari Sridhara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1210, Silver Spring, MD 20903–0002, 301–796–2070; or

Peter Bross, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5378.

SUPPLEMENTARY INFORMATION:

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.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical trial endpoints for the approval of cancer drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9345 Filed 5–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0185]

Draft Guidance for Industry and Review Staff on Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled ''Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to help applicants and the review staff in the Center for Drug Evaluation and Research (CDER) at FDA determine when a drug belongs to an established pharmacologic class as well as how to select the appropriate word or phrase (term) that describes the pharmacologic class for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling.

DATES: Submit written or electronic comments on the draft guidance by August 14, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.