DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Robert W. Pollock
Senior Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. 2006P-0372/CP1

Dear Mr. Pollock:

This letter responds to your citizen petition, dated September 7, 2006, requesting that the Food and Drug Administration (FDA) determine whether MEPRON (atovaquone) tablets, 250 milligrams (mg), the subject of new drug application (NDA) 20-259, were voluntarily withdrawn from sale for safety or effectiveness reasons.

The FDA has reviewed its records and determined that MEPRON tablets, 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain MEPRON (atovaquone) tablets, 250 mg, in the "Discontinued Drug Product List" section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-2041.

Sincerely,

Christine F. Rogers
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2006P-0372

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