

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:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated September 7, 2006. Your petition requests that the Agency 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Mepron (atovaquone) tablets, 250 milligrams (mg), the subject of new drug application (NDA) 20-259, were voluntarily withdrawn from sale for safety or effectiveness reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

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