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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 5 2006

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Sidney Wolfe, M.D.
Elizabeth Barbehenn, Ph.D.
Public Citizen Health Research Group
1600 20th Street, N.W.
Washington, D.C. 20009

Re: Docket No. 2006P-0154/CP1

Dear Dr. Wolfe and Dr. Barbehenn:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 10, 2006. Your petition requests that FDA immediately remove the prescription version of Xenical (orlistat) from the market based on data described in the NDA reviews and a recent study that reported an association between orlistat and an increased incidence of colonic aberrant crypt foci in rats. Your petition also opposed allowing orlistat to be marketed as an over-the-counter drug product.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0154

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