305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 4 2003

6093 '03 SEP -9 A9:43

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street NW
Washington, DC 20009-1001

Re: Docket No. 03P-0090/CP1

Dear Dr. Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on March 6, 2003. Your petition requests that FDA remove Serzone (nefazodone) from the market for safety reasons.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by FDA 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

03P-0090

LET 1