DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 22 2006

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

Re: Docket No. 2006P-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 received on February 28, 2006. Your petition requests that FDA immediately begin the phased removal from the market of propoxyphene (Darvon) and all propoxyphene-containing products 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 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

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