



FEB 3 2006

0092 6 FEB -6 P152

David S. Lowe
5059 Secor Road
Ida, Michigan 48140

Re: Docket No. 2005P-0323/CP 1

Dear Mr. Lowe:

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 August 12, 2005. Your petition requests that the Agency remove Adderall and Adderall XR from the market due to the risk of sudden unexplained death in children.

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
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0323

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