



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 27 2004

Food and Drug Administration
Rockville MD 20857

Richard Blumenthal
Attorney General
Office of the Attorney General
State of Connecticut
55 Elm St.
P.O. Box 120
Hartford, CT 06141-0120

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Re: Docket No. 2004P-0043/CP1

Dear Mr. Attorney General:

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 January 23, 2004. Your petition requests that we require Purdue Pharma L.P. to revise the labeling of OxyContin (oxycodone hydrochloride, extended release tablets) to include additional information and warnings about the risks of taking the drug at more frequent intervals than is recommended in the current labeling for OxyContin.

We have been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by FDA officials. This interim response is provided in accordance with our 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

2004P-0043

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