



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

Food and Drug Administration
Rockville MD 20857

1256 5 DEC 27 P1:48

DEC 22 2005

James Salsman
1910 Mt. Vernon Court, Apt. 3
Mountain View, CA 94040

Re: Docket No. 2005P-0265

Dear Mr. Salsman:

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 June 27, 2005. Your petition requests that the Agency switch modafinil from a prescription to an "over-the-counter" drug product.

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-0265

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