DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 29 2006

David G. Adams
Veneble LLP
575 7th Street, NW
Washington, DC 20004-1601

Re: Docket No. 2006P-0001/CP1

Dear Mr. Adams:

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 January 3, 2006. Your petition requests that FDA: (1) confirm the approval of the NDA for Lunesta (eszopiclone) became effective on April 4, 2005; (2) confirm that the 5 year exclusivity for Lunesta commenced on April 4, 2005; and (3) confirm that the patent term extension for Lunesta should be calculated based on the effective approval date of April 4, 2005.

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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