DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 11 2006

John P. O'Donnell
Mylan Laboratories Inc.
1500 Corporate Drive, Suite 400
Canonsburg, PA 15317-8574

Re: Docket No. 2006P-0123/CP1

Dear Mr. O'Donnell:

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 March 17, 2006. Your petition requests that the Agency require all applicants and holders of approved applications for fentanyl transdermal delivery systems (patches) to (1) conduct a study to support the safe use of an overlay with their patches and (2) include information in their labeling regarding the type of overlay(s) that may be used with their respective fentanyl patches.

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

2006P-0123

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