HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 2 3 2007

Food and Drug Administration
Rockville MD 20857

John P. O'Donnell, Ph.D.
Mylan Laboratories Inc.
P.O. Box 4310
781 Chestnut Ridge Road
Morgantown, WV 26504-4310

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Re: Docket No. 2006P-0290/CP1

Dear Dr. 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 July 24, 2006. Your petition requests that the FDA determine whether a risk management program is necessary for fentanyl transdermal delivery systems. If so, you request that FDA develop and adopt a unified, comprehensive management program for all fentanyl drug products with the participation of all sponsors of approved marketing applications for these products.

FDA has been unable to reach a decision on your petition because it raises significant 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-0290

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