



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

July 24, 2006

**FILE COPY**

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

Dear Dr. O'Donnell:

Your petition requesting the Food and Drug Administration to determine the necessity for a Risk Management Program for transdermally administered fentanyl drug products, was received by this office on 07/24/2006. It was assigned docket number 2006P-0290/CP1 and it was filed on 07/24/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P0290

ACK 1