



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 30, 2004

Dr. Steven L. Shafer
VA Palo Alto Health Care System
Anesthesiology Service (112A)
3801 Miranda Avenue
Palo Alto, California 94304

FILE COPY

Dear Dr. Shafer:

Your petition requesting the Food and Drug Administration to request specific action on the regulation of generic transdermal fentanyl delivery systems, and to request similar attention to new product approvals for transdermal fentanyl products, was received by this office on 07/29/2004. It was assigned docket number 2004P-0340/CP 1 and it was filed on 07/30/2004. 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 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

2004 P-0340

ACK 1