



Food and Drug Administration
Rockville, MD 20857

October 19, 2005

FILE COPY

Gary D. Colby, Ph.D., J.D.
Duane Morris LLP
30 South 17th Street
Philadelphia, Pennsylvania 19103

Dear Dr. Colby:

Your petition requesting the Food and Drug Administration to re-evaluate the prescribing information/package insert for new tramadol formulations in light of currently available safety information, was received by this office on 10/19/2005. It was assigned docket number 2005P-0421/CP1 and it was filed on 10/19/2005. 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,

Glorie Ortega
for Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0421

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