



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

March 13,2007

Peter R. Mathers  
Kleinfeld, Kaplan and Becker, LLP  
1140 Nineteenth Street, N.W.  
Washington, DC 20036-6606

Dear Mathers:

Your petition submitted on behalf of Perdue Pharma L.P. requesting the Food and Drug Administration to refuse to approve CIP-TRAMADOL ER until Cipher complies with the investigations reports to show the safety and effectiveness of the drug, was received by this office on 03/13/2007. It was assigned docket number 2007P-0093/CP1 and it was filed on 03/13/2007. 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,

Gloria Ortega  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2007P-0093

ACK 1