



Food and Drug Administration  
Rockville, MD 20857

April 4, 2005

**FILE COPY**

Mr. Peter O. Safir  
Covington and Burling  
1201 Pennsylvania Avenue, N.W.  
P.O. Box 7566  
Washington, D.C. 20004-2401

Dear Mr. Safir:

Your petition requesting the Food and Drug Administration to refuse to approve abbreviated new drug applications (ANDAs) referencing Arava (leflunomide) tablets, was received by this office on 03/31/2005. It was assigned docket number 2005P-0127/CP 1 and it was filed on 04/01/2005. 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,

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