



SEP 25 2002

1009 6 27 11 40

Sidney M. Wolfe, M.D.
Director, Public Citizen
1600 20th Street, N.W.
Washington, D.C. 20009

Re: Docket No. 02P-0139/CP1

Dear Dr. Wolfe:

This letter responds to your citizen petition dated March 28, 2002, requesting that the Food and Drug Administration (FDA) withdraw approval of Arava (leflunomide), a drug for the treatment of rheumatoid arthritis.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,


for Janet Woodcock, M.D.

Director
Center for Drug Evaluation and Research

02P-0139

LET