



AUG 31 2005

Food and Drug Administration
Rockville MD 20857

4 4 2 4 5 SEP -6 P 3 :06

Elizabeth Barbehenn, Ph.D.
Peter Lurie, M.D., M.P.H.
Sidney Wolfe, M.D.
Public Citizen Health Research Group
1600 20th Street, N.W.
Washington, DC 20009-1001

Re: Docket No. 2005P-0094/CP1 and SUP1

Dear Drs. Barbehenn, Lurie, and Wolfe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition and supplement received on March 4 and April 28, 2005, respectively, regarding the drug Iressa (gefitinib). Iressa was approved by FDA on May 5, 2003, under Subpart H of FDA regulations (21 CFR 314.500-560), as a third-line treatment for non-small cell lung cancer (NSCLC) based on objective response rates (tumor response). Your petition requests that FDA immediately remove Iressa from the market because confirmatory clinical trials conducted by Iressa's sponsor pursuant to 21 CFR 314.510 have failed to verify Iressa's clinical benefit in extending survival of patients with NSCLC.

As you know, on June 17, 2005, FDA announced that the drug's sponsor, AstraZeneca Pharmaceuticals, LP, agreed to take certain steps relating to the marketing of Iressa, including narrowing the labeled indication, and limiting distribution through a risk management plan primarily to those patients who have previously demonstrated a response to Iressa. A detailed description of these steps is available at: <http://www.fda.gov/cder/drug/infopage/gefitinib/default.htm>.

FDA has been unable to reach a decision on your petition because it raises significant 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,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0094

LET 1