DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-399/S-008

AstraZeneca Pharmaceuticals LP
Attention: Patricia Palumbo, RN, BSN, JD
Regulatory Affairs Director
1800 Concord Pike P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Palumbo:

Please refer to your supplemental new drug application dated March 28, 2005, received March 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Iressa (gefitinib) Tablets.

We acknowledge receipt of your submissions dated May 24 and 25; and June 9, 2005.

This supplemental new drug application provides for revised labeling. Specifically, this labeling includes revisions to the CLINICAL STUDIES and INDICATIONS AND USAGE sections to reflect the results of Trial 709 in non-small cell lung cancer (NSCLC), which failed to demonstrate an increase in survival.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-399/S-008**." Approval of this submission by FDA is not required before the labeling is used.

You have stated that you will limit distribution of this drug under a risk management plan called the Iressa Access Program, to the following patient populations:

- patients currently receiving and benefiting from Iressa;
- patients who have previously received and benefited from Iressa; and
- previously enrolled patients or new patients in non-IND clinical trials approved by an IRB prior to June 17, 2005.

Marketing of this drug product and related activities are to be in accordance with the substance and procedures of all FDA regulations and the commitments you have made regarding the Iressa Access Program.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Amy Baird, Regulatory Project Manager, at (301) 594-5779.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur
6/17/05 09:18:37 AM