DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-399/S-005

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 May 13, 2004, received May 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IRESSA (gefitinib tablets).

This supplemental new drug application provides for changes to the package insert that include language relative to myelotoxicity observed in studies using the combination of IRESSA and vinorelbine; and hemorrhagic events, particularly epistaxis and hematuria.

We 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 labeling contained in your submission dated May 13, 2004.

The final printed labeling (FPL) must be identical to the submitted labeling.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-399/S-005." Approval of this submission by FDA is not required before the labeling is used.

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

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

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