The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB, which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **AstraZeneca Canada Inc**. Contact the company for a copy of any references, attachments or enclosures.

PUBLIC COMMUNICATION
Health Canada Endorsed Important Information on IRESSA® (gefitinib) 250 mg tablets

June 5, 2006

Subject: Health Canada Restricts the Indication for IRESSA® (gefitinib) to lung cancer patients who currently benefit from IRESSA therapy and whose tumours are EGFR Positive or unknown.

AstraZeneca Canada Inc., in consultation with Health Canada, would like to inform you of new restrictions on the use of IRESSA. An important study showed that treatment with IRESSA does not prolong survival in patients who have failed one or two prior chemotherapies, or were intolerant to these treatments. Though the study did not show IRESSA being associated with any new side-effects, due to lack of demonstrated benefit in extending survival and the previously disclosed risks that are associated with the use of IRESSA, only patients that are currently benefiting from IRESSA treatment and whose tumours are Epidermal Growth Factor Receptor (EGFR) positive or unknown should receive this drug. No new patients will be prescribed IRESSA. It is recommended that patients review the use of IRESSA in their treatment plans with their own physicians.

IRESSA will continue to be available to currently benefiting patients. Patients must be registered into the IRESSA Patient Registry. Please contact the IRESSA Patient Registry at 1-866-473-7720 for more details. Registration takes place by the pharmacist when patients go to the pharmacy to fill the prescription for IRESSA. This will ensure uninterrupted and continuing access to therapy.

If patients are in a clinical trial for IRESSA and receive IRESSA directly from their physician, access to the drug does not change.

Any suspected adverse drug reaction can be reported to:

AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, ON L4Y 1M4 T
Tel: 1-800 433-0733
Fax: 1-800-267-5743
www.astrazeneca.ca

Any suspected adverse drug reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335

To report an Adverse Reaction (AR), consumers and Health professional may call toll free:

Tel: (866) 234-2345
Fax: (866) 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

For other inquiries related to this communication, please contact Health Canada at:

Therapeutics Products Directorate
Telephone: (613) 941-3171
Fax: (613) 941-1365
E-mail: BMORS_Enquiries@hc-sc.gc.ca

Should you have any questions or require additional information regarding IRESSA®, please contact your health care provider (physician, nurse or pharmacist) or AstraZeneca Medical Information at 1-800-668-6000 (English) and/or 1-800-461-3787 (French).