DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 27 1999

Donna M. Dea
Assistant Manager, Marketed Products
Zeneca Pharmaceuticals
1800 Concord Pike
Wilmington, De 19850-5437

RE: NDA 20-541
Arimidex (anastrozole) tablets
MACMIS ID# 7879

Dear Ms. Dea:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Arimidex (anastrozole) tablets that are misleading. Reference is made to a slim jim brochure (AI1045), submitted under cover of Form FDA 2253 on June 9, 1999 and two journal advertisements (AI1051 and AI1052), submitted on April 8, 1999. The dissemination and/or publication of these materials by Zeneca Pharmaceuticals (Zeneca) violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. DDMAC requests that the use of the above referenced materials and those containing similar promotional claims or presentations cease immediately.

Misleading Survival Presentation

Without qualifying context, the statements, "The 2-year survival rate for patients treated with Arimidex (anastrozole) 1 mg vs those treated with megestrol acetate was 56.1% and 46.3%, respectively" and "Patients treated with Arimidex 1 mg had a median overall survival of 26.7 months vs 22.5 months for patients treated with megestrol acetate" are misleading because they suggest that there is a survival advantage with Arimidex versus megestrol acetate that has not been demonstrated by substantial evidence. Importantly, with regard to survival, qualifying language from the approved product labeling states, "similar results were observed among treatment groups and between the two trials" and "None of the within trial differences were statistically significant." Therefore, Zeneca's suggestion that patients on Arimidex have

a survival advantage over those on megestrol acetate is misleading.

Misleading Drug Interaction Statement

The claim, "New data demonstrate that there is no pharmacokinetic interaction when Arimidex and Nolvadex (tamoxifen citrate) are administered together" is misleading for two reasons. First, this claim is misleading because the referenced study does not provide adequate substantiation. The study was inadequately powered to detect the changes, or lack thereof, that would provide support for the conclusions drawn. Moreover, the study was conducted in only thirty-four patients and the patient population studied (post-menopausal women with early breast cancer) was inappropriate since Arimidex is indicated after disease progression following tamoxifen therapy in advanced breast cancer. Therefore, the design of the study was inadequate to provide significant support for the conclusions drawn.

Zeneca should immediately cease using this and all other promotional materials for Arimidex that contain the same or similar claims or presentations. Zeneca should submit a written response to DDMAC, on or before October 11, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Zeneca should include a list of all promotional materials that were discontinued, and the discontinuation date.

Zeneca should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Zeneca that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7879 and NDA 20-541.

Sincerely,

/S/

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications