DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT - 1 1997

TRANSMITTED VIA FACSIMILE

Ms. Donna M. Dea
Assistant Manager, Marketed Products Group
Drug Regulatory Affairs Department
Zeneca Pharmaceuticals
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

RE: NDA# 20-547
Accolate (zafirkulast) Tablets
MACMIS ID# 5861

Dear Ms. Dea:

This letter from the Division of Drug Marketing, Advertising, and Communications (DDMAC) to Zeneca Pharmaceuticals (Zeneca) concerns several

DDMAC has determined that these ads contain unsubstantiated implied efficacy claims for an unapproved use that are misleading and present potential safety issues, as well as lack fair balance. Therefore, these ads are violative of the Federal Food, Drug, and Cosmetic Act ("Act") and its implementing regulations. DDMAC's concerns were expressed to Zeneca in telephone discussions on September 29, 1997, and September 30, 1997, during which DDMAC requested Zeneca immediately cease dissemination of these In addition, the

Unsubstantiated Implied Efficacy Claims for an Unapproved Use

The ads contain a collection of
hat misleadingly suggest that Accolate is

DDMAC previously discussed this issue with Zeneca during product launch and subsequent advisory request for comment on direct-to-consumer ads, letters dated September 27, 1996, and March 13, 1997. In those letters, DDMAC advised Zeneca that

Moreover, such broad

Such implied messages are inconsistent

Risk Information

The do not include an

As expressed, consumers would take this message to refer to

Furthermore, this risk message is minimized by its placement

In addition, the placement of these important risk messages subsequent to disclosure of

Finally, as discussed above,

Advertisement

The associated
Individuals who

it is violative of the Act and its implementing regulations.

On September 29, 1997, DDMAC requested Zeneca to discontinue disseminating these violative On September 30, 1997, Zeneca stated it would make arrangements to discontinue the as soon as possible. DDMAC requests a written confirmation of the date of discontinuation and a listing of commercial placements discontinued, as well as a commitment to discontinue

Zeneca's written response should be received no later than October 16, 1997. Zeneca's response should be directed to the undersigned at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Zeneca that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS# ID 5861 in addition to the NDA number.

Sincerely,

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications