DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOT

Food and Drug Administration
Rockville MD 20857

APR - 1 1998

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#: 6485

Dear Ms. Dea:

It has come to the attention of the Division of Drug Marketing, Advertising, and Communications (DDMAC) that Zeneca Pharmaceuticals (Zeneca) has disseminated a four-page journal ad for Accolate (zafirkulast) Tablets (AC-1121) that lacks fair balance and is misleading and therefore violates the Federal Food, Drug, and Cosmetic Act and implementing regulations.

On two pages of this ad, Zeneca includes the following safety claims and descriptive footnote:

"Clinical Experience Says So..."

"• Generally well tolerated in clinical studies. No liver function monitoring required§"

> "§: For more information, see brief summary of full prescribing information, especially PRECAUTIONS and ADVERSE REACTIONS sections."

The ad fails to present a fair balance between information relating to side effects and contraindications (including warnings and precautions) and information relating to effectiveness of the drug. Furthermore, misleading safety claims in one part of the ad are not corrected by a brief summary of the full prescribing information (including side effects, contraindications, warnings and precautions) in another distinct part of the ad.

Zeneca should cease its dissemination and use of promotional materials that contain these and similarly violative presentations. Zeneca should respond in writing no later than April 15, 1998,

and should include a list of all similarly violative materials and a description of its method of discontinuing its use. 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 6485 in addition to the NDA number.

Sincerely,

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