DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

APR - 4 1997

TRANSMITTED VIA FACSIMILE

Suzanne E. LoGalbo, R.Ph., J.D.
Associate Director, Drug Regulatory Affairs
Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5755

RE: NDA# 19-835
Zyrtec (cetirizine HCl) Tablets
MACMIS ID# 5232

Dear Ms. LoGalbo:

As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional material (journal ad CLO86A97) for Zyrtec (cetirizine HCl) Tablets that is misleading or is otherwise violative of the Federal Food, Drug, and Cosmetic Act and regulations.

The journal ad entitled "BIG Allergies. BIG Relief" lacks fair balance and is therefore misleading. The ad is formatted in three pages: The first page is graphics only; the second page facing the first page features graphics and textual product claims, and the third page includes graphics, the headline "BIG ALLERGY RELIEF", risk information including Zyrtec's side effect profile, and the brief summary. The journal ad lacks fair balance because it fails to present risk information with a prominence and readability reasonably comparable to the presentation of the drug effectiveness claims.

Pfizer should immediately cease it use of promotional materials that contain this or similar presentations. Pfizer's written response should include a description of its plan to address this issue. Pfizer's written response should be received by DDMAC no later than April 18, 1997, and should be directed to the undersigned 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 Pfizer that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5232 in addition to the NDA number.

Sincerely,

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

File Name: zyrtec\hcpbig.nov

Drafted: HANKIN Date: 3/24/97
Concur: ABRAMS Date: 3/31/97

HFD-40/NDA # 19-835
HFD-40/Chron/HANKIN(2)/ABRAMS
HFD-570/NDA # 19-835

MACMIS ID # 5232

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253# Material ID#: CLO86A97

Due Date: April 18, 1997

Close Out: N

FOI STATUS: RELEASABLE