DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR -4 1998

TRANSMITTED VIA FACSIMILE

Mr. Stephen Cristo
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#: 6368

Dear Mr. Cristo:

This letter from the Division of Drug Marketing, Advertising, and Communications (DDMAC) concerns promotional materials for Zyrtec (cetirizine HCl) Tablets and Syrup that feature comparative pharmacodynamic claims (e.g., brochure CL172V07A). DDMAC has determined that these promotional materials contain unsubstantiated implied clinical superiority claims and are therefore violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Under the headlines, "BIG Activity...That starts fast"/(Data on File) and "BIG Activity...That lasts"/(cite: Simons et al), Pfizer presents graphical differences in pharmacodynamic data for Zyrtec Tablets, Claritin (loratadine) Tablets, Seldane (terfenadine) Tablets, and Hismanal (astemizole) Tablets, based on the wheal/flare suppression test. This *in vivo* test demonstrates pharmacological activity (i.e., inhibition of the skin's wheal and flare response of an epicutaneous injection of histamine in normal volunteers) rather than clinical efficacy in patients with the indicated diseases.

The presentations of comparative pharmacodynamic data are misleading because they suggest clinical significance, including clinical superiority, based on these pharmacologic effects when no such clinical relevance has been demonstrated by substantial evidence (i.e., adequate and well-controlled clinical studies) for some or all of the competitive products.

DDMAC requests that the distribution and use of Zyrtec promotional materials containing these and similar misleading comparative presentations cease immediately. DDMAC requests that Pfizer's written response be received by DDMAC no later than March 18, 1998, and should include a list of all violative materials and a description of its method of discontinuing their use.

Please direct your response to the undersigned by facsimile 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, Maryland 20857. DDMAC reminds Pfizer that only written communications are considered official.

In future correspondence regarding this particular matter, please refer to MACMIS ID# 6368 in addition to the NDA number.

Sincerely,

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