May 15, 1998

NDA 19-835/S-005

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: Rita A. Wittich
Director, Regulatory Affairs

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated May 29, 1997, received June 3, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine HCl) Tablets.

We acknowledge receipt of your submissions dated January 16, April 28, and May 14, 1998. The user fee goal date for this application is June 3, 1998.

The supplemental application, as amended, provides for the use of Zyrtec in pediatric patients 2-5 years of age for the indications seasonal and perennial allergic rhinitis and chronic idiopathic urticaria.

We have completed the review of this supplemental application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated May 14, 1998. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on May 14, 1998.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 19-835/S-005." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a Dear Doctor letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research