DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-835/S-016, 21-150/S-005 and 20-346/S-011

Pfizer Global Pharmaceuticals
235 East 42nd Street
New York, NY 10017

Attention: Robert Clark
Vice President, Drug Regulatory Affairs

Dear Dr. Wire:

Please refer to your supplemental new drug applications dated August 29, 2003, received September 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine hydrochloride) Tablets, Zyrtec (cetirizine hydrochloride) Syrup, and Zyrtec-D (cetirizine hydrochloride 5mg and pseudoephedrine hydrochloride 120mg) Extended Release Tablet .

These "Changes Being Effected" supplemental new drug applications provide for the addition of aggressive reactions and convulsions to the ADVERSE REACTIONS section of the package inserts.

We completed our review of these supplemental new drug applications, they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 29, 2003. As agreed to in a telephone conversation between Sandy Barnes of this Agency and Samantha Wolfe of your company, you will make the revisions shown in the attached package inserts at the next printing.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Lori Garcia, Regulatory Project Manager, at (301) 827-5580.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
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