



NDA 19-835/S-015

NDA 20-346/S-008

Pfizer Pharmaceuticals  
235 East 42<sup>nd</sup> Street - 150/7/12  
New York, NY 10017

Attention: John P. Kennedy  
Director, Worldwide Regulatory Strategy

Dear Mr. Kennedy:

Please refer to your supplemental new drug applications dated December 21, 2001, received December 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine hydrochloride) Tablets, 5 and 10 mg, and Syrup, 1mg/ml.

We acknowledge receipt of your submissions dated December 21, 2001, and January 30, February 20, March 18, June 20, August 26 and 30, September 25, October 9, 10, 14, and October 21, 2002.

These supplemental new drug applications provide for the use of Zyrtec (cetirizine hydrochloride) Tablets and Syrup for the relief of symptoms associated with perennial allergic rhinitis in adults and children 6 months of age and older.

These supplemental new drug applications also provide for the use of Zyrtec (cetirizine hydrochloride) Tablets and Syrup for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions indicated in the enclosed labeling. Accordingly the applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted October 21, 2002). These revisions are terms of the approval of these applications.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 heavyweight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 19-835/S-015, NDA 20-346/S-008." Approval of these submissions by FDA is not required before the labeling is used.

NDA 19-835/S-015

NDA 20-346/S-008

Page 2

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dr. Craig Ostroff, Regulatory Management Officer, at 301-827-5585.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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/s/

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Badrul Chowdhury  
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