



NDA 19-835/S-020

Pfizer Inc
235 East 42nd Street 150/7/9
New York, NY 10017

Attention: Samantha McNamara
Director, U.S. Regulatory Affairs

Dear Ms. McNamara:

Please refer to your supplemental new drug application dated October 3, 2005, received October 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine HCl) Tablets, 5mg and 10mg.

We acknowledge receipt of your submissions dated February 3 and 6, and March 6, 2006.

Your submission of February 6, 2006, constituted a complete response to our February 3, 2006, action letter.

This supplemental new drug application provides for the manufacture of Zyrtec 5mg and 10mg tablets using (b) (4) [redacted], and for a change to (b) (4) [redacted].

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling [text for the package insert submitted March 6, 2006 (copy enclosed)].

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-835/S-020.**" Approval of this submission by FDA is not required before the labeling is used.

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 Lori Garcia, Regulatory Project Manager, at (301) 796-1212.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary Allergy 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
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/s/

Badrul Chowdhury
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