DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-150/S-002

Pfizer Pharmaceuticals
Pfizer, Inc.
235 East 42nd Street 150/7/6
New York, NY 10017

Attention: Denise F. Andrews
Director, Worldwide Regulatory Strategy

Dear Ms. Andrews:

Please refer to your supplemental new drug application dated June 13, 2002, received June 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec-D 12 Hour (cetirizine HCl 5 mg and pseudoephedrine HCl 120 mg) Extended Release Tablets.

We acknowledge receipt of your submissions dated November 26, 2002, January 27 and 30, February 4 and 13, March 27, and April 4 and 9, 2003.

This supplemental new drug application provides additional safety and efficacy information for inclusion in the Zyrtec-D 12 Hour Extended Release Tablet labeling.

We have 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 April 9, 2003).

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, this submission should be designated "FPL for approved supplement NDA 21-150/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 this NDA 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.
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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