NDA 21-150

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

Attention: John Tomaszewski, M.S.
Director, Regulatory Affairs

Dear Mr. Tomaszewski:

Please refer to your new drug application (NDA) dated January 18, 2000, received January 19, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec-D 12 Hour (cetirizine hydrochloride 5 mg and pseudoephedrine hydrochloride 120 mg) Extended Release Tablets.

We acknowledge receipt of your submissions dated April 7, May 12, June 5, August 16, September 29, October 11 and 17, November 21 and 29, December 12 and 27, 2000, and January 17 and 18, February 12, 15, 20, and 28, March 27 and 28, April 23 and 27, July 26, and August 7, 2001. We further acknowledge receipt of your correspondence dated July 26, 2001. Your submission of February 12, 2001, constituted a complete response to our January 17, 2001, action letter.

This new drug application provides for the use of Zyrtec-D 12 Hour (cetirizine hydrochloride 5 mg and pseudoephedrine hydrochloride 120 mg) Extended Release Tablets for the relief of nasal and non-nasal symptoms associated with seasonal or perennial allergic rhinitis in adults and children 12 years of age and older.

We have completed the review of this application, as amended, 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert, immediate container and carton labels submitted July 26, 2001. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

(b)(4)----------

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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 NDA 21-150." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). You have fulfilled the pediatric study requirement at this time for pediatric patients 12 years of age and older. A waiver for pediatric studies for patients below 12 years of age is granted at this time for this action.

In addition, please submit three copies of the introductory promotional materials 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 materials and the package insert directly to:

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

Please submit one market package of the drug product when it is available.

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 Dr. Craig Ostroff, Regulatory Management Officer, at 301-827-5585.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Marianne Mann
8/10/01 10:55:29 AM
Dr. Mann is signing as Acting Director in the absence of Dr. Meyer, the Division Director.