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APPLICATION NUMBER:

21-621

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-621

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

Attention: Robert Clark
Vice President, US Regulatory Affairs

Dear Mr. Clark:

Please refer to your new drug application (NDA) dated May 15, 2003, received May 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyrtec (cetirizine HCl) Chewable Tablets, 5 mg and 10 mg.

We acknowledge receipt of your submissions dated September 15, 19, and 30, October 13, and 31 (2), November 26, and December 17, and 24, 2003, and February 25, and March 8, 11, and 12, 2004.

We completed our review of this application, as amended. It 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 (package insert submitted March 12, 2004, and immediate container and carton labels submitted March 8, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-621.**" Approval of this submission by FDA is not required before the labeling is used.

Your amendment dated February 25, 2004, contains the following agreements:

1. I(b)(4)-----in the drug product. These (b)(4)----- will be reassessed following the review of twelve months' stability data generated from the first three commercial lots of each strength and 36 months' stability data generated from the primary stability lots. When this action item is completed, submit a report including a proposal for approval of final degradant acceptance criteria in the drug product.
2. I(b)(4)-----
(b)(4)----- Perform a simulated in-use study using tablets of varying hardness

(including the lower limits) which will be pushed-through the commercial peel/push blister to ensure no breakage occurs. Submit the results of this study and a proposal for approval of final hardness limits within twelve months of approval of this NDA.

3. Provide samples of commercial blister packs for each strength within approximately six weeks of approval of this NDA.

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. We are waiving the pediatric study requirement for zero to less than 2 years of age for this application. We note that you have fulfilled the pediatric study requirement for ages 2 years to adults for this application.

If you have any questions, call Lori Garcia, Regulatory Management Officer, at (301) 827-5580

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Badrul Chowdhury
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