



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 77-499

Caraco Pharmaceutical Laboratories Ltd.  
Attention: Veeranna Lolla  
Sr. Manager, Regulatory Affairs  
150 Elijah McCoy Drive  
Detroit, MI 48202

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cetirizine Hydrochloride Tablets (OTC), 5 mg and 10 mg.

Reference is also made to the tentative approval letter issued by this office on May 29, 2007, and to your amendments dated July 6, September 23, and December 13, 2005; and September 26, December 4, December 5, December 7, December 19, and December 20, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted over-the counter (OTC) labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Cetirizine Hydrochloride Tablets, 5 mg and 10 mg, to be bioequivalent to the reference listed drug, Zyrtec Allergy Tablets, 5 mg and 10 mg, and Zyrtec Hives Relief Tablets, 5 mg and 10 mg, of Pfizer Pharmaceuticals Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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

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Robert L. West  
12/27/2007 12:55:07 PM  
for Gary Buehler