



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-047

Par Pharmaceutical, Inc.
Attention: Linda Kulick
Regulatory Affairs
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 7, 2000, 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 October 6, 2004, and to your amendments dated March 14, 2001; June 13, 2006; and October 8, December 6, and December 18, 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 (OTC), 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

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

/s/

Robert L. West
12/27/2007 12:52:42 PM
for Gary Buehler