DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-946

Sandoz Inc.
Attention: Carmelle Lucas, Ph.D.,
Director, Regulatory Affairs
506 Carnegie Center, Suite 400
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 19, 2005, 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 your amendments dated May 31, 2006; and January 22, April 23, September 4, and October 3, December 4, December 5, December 6, December 12, and December 19, 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 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

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 12:54:36 PM
for Gary Buehler