DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-631

Caraco Pharmaceutical Laboratories, Ltd.
Attention: Veeranna Lolla
Sr. Manager, Regulatory Affairs
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 24, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cetirizine Hydrochloride Chewable Tablets, 5 mg and 10 mg (OTC).

Reference is also made to the tentative approval letter issued by this office on October 4, 2007, and to your amendments dated September 26, and December 28, 2005; March 10, 2006; and October 5, December 4, December 6, December 7, 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 Chewable Tablets, 5 mg and 10 mg (OTC), to be bioequivalent to the reference listed drug (RLD), Zyrtec Allergy Tablets (Chewable), 5 mg and 10 mg, and Zyrtec Hives Relief Tablets (Chewable), 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.

The RLD upon which you have based your ANDA, Pfizer's Zyrtec Allergy Tablets (Chewable), 5 mg and 10 mg, and Zyrtec Hives Relief Tablets (Chewable), 5 mg and 10 mg, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Number 6,455,533 (the '533 patent) is scheduled to expire on July 2, 2018.

Your ANDA contains a paragraph IV certification to the '533 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Cetirizine Hydrochloride Chewable Tablets, 5 mg and 10 mg,(OTC) under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Caraco Laboratories, Ltd. (Caraco) for infringement of the '533 patent. You have notified the agency that Caraco complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '533 patent was brought against Caraco within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

FDA has determined that Caraco was the first applicant to submit a substantially complete application that contained a paragraph IV certification to the '533 patent for Cetirizine Hydrochloride Chewable Tablets, 5 mg and 10 mg (OTC), and therefore, was eligible for 180-day generic-drug exclusivity under section 505(j)(5)(B)(iv) of the Act. However, due to the following set of circumstances, your eligibility for 180-day exclusivity was forfeited under section 505(j)(5)(D)(i)(IV).

Your ANDA was received by the agency on March 25, 2005, and granted tentative approval on October 4, 2007. The ANDA filing date plus 30 months was September 25, 2007; therefore, this ANDA was not granted tentative approval within the 30 month period described in section 505(j)(5)(D)(i)(IV). We also have determined that the requirements for approval of this ANDA were not changed or reviewed after your application was filed, nor was a related citizen petition submitted that would extend the 30-month period as described in section 505(q)(1)(G) of the Act. We therefore conclude that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act for Cetirizine Hydrochloride Chewable Tablets 5 mg and 10 mg (OTC) was forfeited by Caraco.

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
1/11/2008 09:06:52 AM
for Gary Buehler