DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 079191

Torrent Pharma Inc.
U.S. Agent for: Torrent Pharmaceuticals Limited
Attention: Dawn Chitty
Director, Regulatory Affairs
5380 Holiday Terrace, Suite 40
Kalamazoo, MI 49009

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 29, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cetirizine Hydrochloride Tablets, 5 mg and 10 mg (OTC).

Reference is also made to your amendments dated October 17, 2008; and February 23, and March 10, 2010.

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 over-the-counter (OTC) 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 McNeil Consumer Healthcare. 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. For administrative purposes, please designate this submission as "***LABELING/SPL FINAL for Approved ANDA 079191***".

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research