DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 90-300

Beckloff Associates, Inc.
U.S. Agent for: Cypress Pharmaceutical, Inc.
Attention: William C. Putnam., Ph.D., R.A.C.
Director, Executive Consultant
Commerce Plaza II, Suite 300
7400 West 110th Street
Overland Park, KS 66210

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 25, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Children's Cetirizine Hydrochloride Oral Solution (Allergy) and Children's Cetirizine Hydrochloride Oral Solution (Hives-Relief), 1 mg/mL (OTC).

Reference is also made to your amendments dated April 28, April 29, July 23, and September 9, 2008.

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 Children's Cetirizine Hydrochloride Oral Solution (Allergy) and your Children's Cetirizine Hydrochloride Oral Solution (Hives-Relief), 1 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Children's Zyrtec Oral Solution (Allergy) and Children's Zyrtec Oral Solution (Hives-Relief), respectively, 1 mg/mL, of McNeil Consumer Healthcare.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See 505-1(i) of the Act.

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/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 90-300"***.

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
10/10/2008 11:36:43 AM
Deputy Director, for Gary Buehler