DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-157/S-001

UCB, Inc.
1950 Lake Park Drive
Smyrna, Georgia 30080

Attention: Susan Tegtmeyer, M.S.
Senior Manager, Regulatory Affairs

Dear Ms. Tegtmeyer:

Please refer to your supplemental new drug application dated February 12, 2008, received February 13, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyzal (levocetirizine dihydrochloride) oral solution, 0.5 mg/mL.

This supplemental new drug application provides for the correction of the revision date in the RECENT MAJOR CHANGES section of the HIGHLIGHTS OF PRESCRIBING INFORMATION.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the submitted labeling dated February 12, 2008 (copy enclosed).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Badrul Chowdhury
6/25/2008 10:47:02 AM