DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22064/S-017
NDA 22157/S-003

APPROVAL LETTER

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

Attention: Susan Tegtmeyer
Senior Manager, Regulatory Affairs

Dear Ms. Tegtmeyer:

Please refer to your supplemental new drug applications dated February 24, 2009,received February 25, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Xyzal (levocetirizine dihydrochloride) 5mg tablets and 2.5mg/5ml oral solution.

We acknowledge receipt of your submissions to NDA 22-064/S017 dated March 26, June 8, 11, 18, 22, and 24, and July 24 and 27, 2009 and to NDA 22-157 dated February 26, March 26, May 27, June 5, 17, 19, and July 27, 2009.

This supplemental new drug application provides for the use of Xyzal (levocetirizine dihydrochloride) 0.5mg/ml oral solution and 5mg tablets for the relief of symptoms associated with seasonal allergic rhinitis (SAR) in children 2 years of age and older, and for the relief of symptoms of perennial allergic rhinitis (PAR) and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU) for children 6 months of age and older.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the package insert submitted August 17, 2009 (copy enclosed). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission “SPL for approved NDA 22-064/S-017 and NDA 22-157/S-003.”

Marketing this product(s) with FPL that is not identical to the approved labeling text may render this product misbranded and an unapproved new drug.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

LETTERS TO HEALTH CARE PROFESSIONALS
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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS
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, Senior 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
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/

BADRUL A CHOWDHURY
08/21/2009