DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA APPROVAL

NDA 22-157

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

Attention: Patricia Fritz
Vice President
Global Regulatory Affairs

Dear Ms. Fritz:

Please refer to your new drug application (NDA) dated March 27, 2007, received March 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xyzal (levocetirizine dihydrochloride) 0.5mg/mL oral solution.

We acknowledge receipt of your submissions dated June 27, July 18 and 31, September 26, November 6 and 13, 2007, and January 8, 2008.

This new drug application provides for the use of Xyzal (levocetirizine dihydrochloride) 0.5mg/mL oral solution for the relief of symptoms associated with seasonal and perennial allergic rhinitis (SAR and PAR) and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU) for patients 6 years of age and older.

We have completed our review of this application, as amended. 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 submitted labeling (package insert submitted January 8, 2008), 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 22-157."

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted November 13, 2007, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-157**." Approval of this submission by FDA is not required before the labeling is used.

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

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. For Perennial Allergic Rhinitis and Chronic Idiopathic Urticaria, we are waiving the pediatric study requirement for ages 0 to < 6 months and deferring pediatric studies for ages 6 months to < 6 years for this application. For Seasonal Allergic Rhinitis, we are waiving the pediatric study requirement for ages 0 to < 2 years and deferring pediatric studies for ages 2 years to < 6 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of Perennial Allergic Rhinitis in pediatric patients ages 6 months to < 6 years.

   Final Report Submission: January 31, 2010

2. Deferred pediatric study under PREA for the treatment of Chronic Idiopathic Urticaria in pediatric patients ages 6 months to < 6 years.

   Final Report Submission: January 31, 2010

3. Deferred pediatric study under PREA for the treatment of Seasonal Allergic Rhinitis in pediatric patients ages 2 years to < 6 years.

   Final Report Submission: January 31, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments**".

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

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 Lori Garcia, Senior Regulatory Management Officer, at (301) 796-1212.

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

1/28/2008 01:02:04 PM