DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-064

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 July 24, 2006, received July 25, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Xyzal (levocetirizine dihydrochloride) 5mg Tablets.

We acknowledge receipt of your submissions dated August 29 and 31, September 19, October 24 and 31, November 13, 16 and 20, and December 5 and 20, 2006, and January 15, 22 and 26, February 9, March 21, April 2, 23 and 26, and May 2, 14, 15, 22, 23, and 24, 2007.

This new drug application provides for the use of Xyzal (levocetirizine dihydrochloride) 5mg Tablets for the relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children 6 years of age or older, and for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age or older.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

Within 21 days of the date of this letter, submit 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 in content, except for including the revisions indicated in the enclosed labeling, to the submitted labeling dated May 24, 2007. 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."**

Please submit the final printed carton and container labels electronically that are identical to the carton and immediate container labels submitted on May 14, 2007. Alternatively, you may submit 12 paper copies of the final printed carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-064**." Approval of this submission by FDA is not required before the labeling is used. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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. We are waiving the pediatric study requirement for ages 0 to < 2 years and deferring pediatric studies for ages 2 to < 6 years for this the indication of seasonal allergic rhinitis. We are deferring submission of your pediatric studies for ages 0 to < 6 years for the indications of perennial allergic rhinitis and chronic idiopathic urticaria.

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 symptoms of perennial allergic rhinitis in pediatric patients ages 0 to <6 years of age.

   Final Report Submission: May 31, 2009

2. Deferred pediatric study under PREA for the treatment of symptoms of seasonal allergic rhinitis in pediatric patients ages 2 to <6 years of age.

   Final Report Submission: May 31, 2009

3. Deferred pediatric study under PREA for the treatment of chronic idiopathic urticaria in pediatric patients ages 0 to <6 years of age.

   Final Report Submission: May 31, 2009

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**".

We remind you of the agreements made in your submission dated May 15, 2007, to submit the following information to the approved NDA via a CBE-30 supplement. We acknowledge receipt of your submission dated May 22, 2007, containing some of the requested information; however, this submission was not reviewed for this action.

1. ----------
2. Validation report for Method ----------
3. Update of Method ----------
4. Validation report for Method ----------

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

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