



NDA 22-064/S-009

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) 5mg tablets.

This supplemental new drug application provides for revised labeling to include the changes approved under NDA 22-157 on January 28, 2008.

We 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).

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, to the submitted labeling dated February 12, 2008. 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 supplement NDA 22-064/S-009.”**

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 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Badrul Chowdhury  
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