



NDA 022064/S-028  
NDA 022157/S-012

**SUPPLEMENT APPROVAL**

UCB Inc.  
1950 Lake Park Drive, Building 2100  
Smyrna, GA 30080

Attention: Ruta Monoenko  
Senior Manager, Regulatory Affairs

Dear Ms. Monoenko:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 17, 2013, received September 17, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for or the Act) for the following:

<b>NDA#</b>	<b>Supplement#</b>	<b>Product Description</b>
022064	S-028	Xyzal® (levocetirizine dihydrochloride) Tablets
022157	S-012	Xyzal ® (levocetirizine dihydrochloride) Oral Solution

These “Changes Being Effected” supplemental new drug applications propose the following changes:

- Addition of “movement disorders (including dystonia and oculogyric crisis)” to Section 6.2, paragraph 1.
- Addition of “tic, myoclonus, extrapyramidal symptoms” to Section 6.2, paragraph 2.

**APPROVAL & LABELING**

We have completed our review of these supplemental applications. They are 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **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 Nina, Regulatory Project Manager, at (301) 796-1648.

Sincerely,

*{See appended electronic signature page}*

Sally Seymour, M.D.  
Deputy Director for Safety  
Division of Pulmonary, Allergy, and Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE:

Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SALLY M SEYMOUR  
11/07/2013