DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-111/S-015

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

Attention: Anisa Dhalla, Director
Global Regulatory Operations

Dear Ms. Dhalla:

Please refer to your supplemental new drug application dated May 30, 2007, received May 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tussionex® Pennkinetic® (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension.

We acknowledge receipt of your submission(s) dated November 27, 2007, December 13, 2007, February 11, 2008, and March 3, 2008.

Your submission of February 11, 2008, constituted a complete response to our November 28, 2007, action letter.

This "Changes Being Effected" supplemental new drug application provides for changes to the Indications and Usage, Contraindications, and Dosage and Administration sections of the labeling, including minor editorial revisions.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50 (1)] in structured product labeling (SPL) format submitted on March 3, 2008.

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

In addition, we have the following recommendations that refer to your response dated December 13, 2007, to our additional comments in the approvable letter dated November 28, 2007:

1. We acknowledge that the only packaging configuration currently marketed is the 473 mL size. However, because your packing does not include a unit of use configuration, our previously recommended revision to the carton and container labeling and to the specific dosing device would not reach the patient. This could result in medication errors, potentially leading to overdoses and significant adverse reactions. We recommend that you develop a smaller unit-of-use packaging configuration (e.g., a 120 mL bottle) that is packaged in a carton with a dosing device that has been validated to allow for proper dosing. Such a packaging configuration should help to minimize error and confusion associated with the dosing of Tussionex, as the dosing and applicable warnings will be contained on the bottle that is dispensed to the patient/caregiver. The carton labeling should be designed with "white space" for the pharmacy label. This will allow for placement of the pharmacy label on the carton without obscuring the dosing and warnings. We also recommend that you include the patient package insert in the carton with the product and dosing device.

2. We recommend that you pursue other means of communicating applicable warnings and dosing information about this product to patients and caregivers. This should include but is not limited to, working with the companies that provide drug information summaries which appear on pharmacy printouts to ensure that the product information being disseminated directly to the end-user via these printouts, includes the contraindication for patients under 6 years of age.

3. We acknowledge your agreement to make the carton/container warning more prominent by changing the statement to "Contraindicated in children under 6 years of age" bolding the text. To help ensure that this important warning is not overlooked, we recommend that this statement be relocated to the principal display panel and presented in a prominent manner. Additionally, this warning statement should appear prominently on the principal display panel of any new packaging configuration.

4. To help alleviate confusion with the recommended dosing of this drug product and if space allows, we continue to recommend that the dosing information be relocated to the principal display panel and presented in a prominent manner. Addition of this data to the principal display panel is preferred, but if space does not allow, addition of the dosing frequency (every 12 hours) to the principal display panel is acceptable. Additionally, consider prominent placement of the dosing information on the principal display panel of any new packaging configuration that you develop.

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 Philantha Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation
Center for Drug Evaluation and Research

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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