DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-726/S-008

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Kristen Piatak, RAC
Regulatory Affairs Manager
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms Piatak:

Please refer to your Supplemental New Drug Application (sNDA) dated July 30, 2010, received August 2, 2010, submitted under section 505(b) of the Federal Food Drug, and Cosmetic Act (FDCA) for Niravam (alprazolam orally disintegrating tablets) CIV 0.25mg, 0.5mg, 1mg, and 2mg.

We also acknowledge receipt of your email communication dated June 6, 2011.

This Prior Approval supplemental new drug application provides for labeling revisions for Niravam to meet the "Physician Labeling Rule" (PLR) requirements as defined under 21CFR § 201.56 and 201.57.

We have completed our review of this supplemental application. 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, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

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 Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
06/16/2011