DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472/S-005

Banner Pharmacaps Inc.
Attention: Shelly K. Meachum, B.Sc., RAC
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Ms. Meachum:

Please refer to your supplemental new drug application dated January 26, 2005, received January 27, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ibuprofen capsules, 200 mg.

We acknowledge receipt of your submissions dated November 17, 2005 and January 12, 2006.

Your submission of January 12, 2006 constituted a complete response to our November 18, 2005 action letter.

This supplemental new drug application provides for ibuprofen capsules, 200 mg, for the treatment of migraine.

We have 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels submitted November 17, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units** according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-472/S-005**." Approval of this submission by FDA is not required before the labeling is used.

In addition, we have the following recommended revision to your label:

> Increase the size of the arrow symbols and use a contrasting color to increase their prominence to help consumers read the label information in the correct order because of the volume of text and the number of separate panels included in the Drug Facts box on the outer carton.

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 under the age of 12 years and deferring pediatric studies for ages 12 - 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of migraine in pediatric patients ages 12 - 17 years.

   Final Report Submission: March 13, 2009

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, we request that you submit one copy of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print to this division.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

Please submit one market package of the drug product when it is available.

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Andrea Segal

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