CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-920

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-920

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

Dear Ms. Meachum:

Please refer to your new drug application (NDA) dated April 15, 2005, received April 18, 2005, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for naproxen sodium 220 mg capsules.

We acknowledge receipt of your submissions dated May 3, July 28, July 29, and October 14, 2005, and January 4, January 5, and February 9, 2006.

This new drug application provides for the use of naproxen sodium 220 mg capsules for relief of minor aches and pains due to headache, backache, muscular aches, common cold, arthritis, toothache, menstrual cramps, and fever.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (immediate container and carton labels submitted February 9, 2006).

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.

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 reference the partial waiver granted on December 2, 2005 for the pediatric study requirement for ages less than 6 months of age for this application. We also reference the deferral granted on December 2, 2005 for the pediatric study requirement for ages 6 months to 11 years of age 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 fever, minor aches and pains due to the common cold, flu, sore throat, headaches, and toothaches in pediatric patients ages 6 month to 11 years of age.

   Your final report submission is due February 18, 2009.

Submit your final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**". Please submit your pediatric drug development plans within 120 days from the date of this letter.

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 the Division of Nonprescription Clinical Evaluation.

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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