CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-472

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472

Banner Pharmacaps, Inc.
Attention: Ms. Donna Lee, R.Ph.
Director, Regulatory Affairs & Project Management
P.O. Box 2210
4125 Premier Drive
High Point, NC 27265

Dear Ms. Lee:

Please refer to your new drug application (NDA) dated December 14, 2001, received December 18, 2001, 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 January 25 and 28, March 19, May 31, July 10 and 18, August 1, 6, 20, and 22, September 10 and 25, October 1 and 3, 15, 2002.

This new drug application provides for the use of ibuprofen capules, 200 mg for temporary relief of minor aches and pains due to headache, muscle aches, minor pain of arthritis, toothache, backache, the common cold, menstrual cramps and temporarily reduces fever.

We completed our review of this application, as amended. It 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 and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"FPL for approved NDA 21-472".** Approval of this submission by FDA is not required before the labeling is used.

In addition, if any changes to the approved PDP are made they need to be submitted as a prior approval supplement and not as a "Changes Being Effected" supplemental application.

We remind you of your postmarketing study commitment in your submission dated October 3, 2002. This commitment is listed below.

1. Conduct dissolution studies to evaluate the effect of the following lower agitation speeds, 50, 75 and 100 RPM. The results of these studies should be submitted to the Agency by December 1, 2002.

Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates and any changes in plans since the last annual report. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

In addition, we request that you submit two copies 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. Send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, and one to the Division of Over-the-Counter Drug Products.

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).

Oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions, call Walter Ellenberg, Ph. D.Regulatory Project Manager at (301) 827-2222.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Lawerance Goldkind, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Charles Ganley
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APPEARS THIS WAY
ON ORIGINAL