DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021472/S-013 **SUPPLEMENT APPROVAL**

Banner Pharmacaps Inc.
Attention: Vandana Garikipati, MS, RAC
Manager, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Ms. Garikipati:

Please refer to your October 30, 2009 Supplemental New Drug Application (sNDA), received October 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for 200 mg ibuprofen capsules.

We also acknowledge receipt of your submission dated April 9, 2010.

This "Changes Being Effected" supplemental new drug application provides for revised labeling in accordance with the April 29, 2009 final monograph for Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use. This supplemental NDA also provides for the removal of the directions statement "do not take longer than 10 days, unless directed by a doctor (see Warnings)" in response to the FDA September 04, 2009 general advice letter.

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 agreed-upon labeling text.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (Midol Liquid Gels 20-count carton and immediate container (bottle) labels submitted April 9, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021472/S-013**." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21472	SUPPL-13	BANNER PHARMACAPS INC	IBUPROFEN CAPSULES, 200 MG

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

/s/

ANDREA LEONARD SEGAL
04/28/2010