DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472/S-011

Banner Pharmacaps Inc.
Attention: Dana S. Toops
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Mr. Toops:

Please refer to your supplemental new drug application dated August 21, 2008, received August 22, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 200 mg ibuprofen capsules.

(b) (4)

This supplemental new drug application (NDA) provides for the addition of the proprietary name Midol Liquid Gels. This supplemental NDA also provides for revisions to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letters.

We have completed our review of this supplemental new drug application, as amended. This application is approved for the Midol Liquid Gels 20-count package size, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

> The promotional statement "Relief of Cramps, Backache and Muscle Aches" on the principal display panel of the carton label must be revised to read "Temporary Relief of Minor Aches and Pains due to Cramps, Backache and Muscle Aches" at the time of next printing or 180 days, whichever comes first.

Submit final printed labeling, except with the revision listed above, 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 labels (Midol Liquid Gel 20-count immediate container and carton labels submitted November 3, 2008), 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 21-472/S-011**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag “New! Cramps & Body Ache Relief Now in a Liquid Gel” from the principal display panel six months after introduction into the marketplace.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, MD
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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