DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-920/S-011

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 supplemental new drug application dated February 5, 2009, received February 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve Liquid Gels (220 mg naproxen sodium capsules).

This supplemental new drug application provides for a revised label configuration with a pull-out Drug Facts label for the non-child resistant (NCR) count size to be used with a redesigned bottle. The bottle was not submitted for approval as part of this supplement.

We have completed our review of this supplemental new drug application. This application is approved for the label for the NCR Aleve Liquid Gels 80-count package size, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 label (Aleve Liquid Gels 80-count carton label submitted February 5, 2009), 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 21-920/S-011**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that the new bottle shape is not being reviewed or approved under this supplement. Assuming that the change in bottle shape meets the criteria outlined in 21 CFR 314.70, you should report this change in your next annual report. Otherwise, you should submit an appropriate supplemental new drug application for this change.

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}

Joel Schiffenbauer, MD
Deputy 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/

Joel Schiffenbauer
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