DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021920/S-018

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 Supplemental New Drug Application (sNDA) dated October 1, 2012, received October 2, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsules, 220 mg.

We acknowledge receipt of your amendment dated March 15, 2013.

This "Prior Approval" supplemental new drug application proposes the following modifications:

1. Bonus pack labeling statements to indicate the number of free capsules

2. Instant redeemable coupons (IRCs)

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 carton and immediate container (bottle) labels submitted on March 15, 2013:

1. Bonus Statement: X Free Liquid Gels with this Purchase
   - 20-count bottle and carton with IRC (representative of Perrigo's 30-count and Aleve® Liquid Gels 26-count)
   - 40-count bottle and carton with IRC (representative of Perrigo's 50- and 100-count, and Aleve® Liquid Gels 52-, 96-, and 104-count)
   - 80-count non-child resistant bottle and carton with IRC (representative of Aleve® Liquid Gels non-child resistant 96- and 104-count)

2. Bonus Statement: Bonus Size X + Y Free

- 20-count bottle and carton (representative of Perrigo's 30-count)
- 40-count bottle and carton (representative of Perrigo's 50- and 100-count)

3. Bonus Statement: X + Y = Z Liquid Gels
   - 20-count bottle and carton (representative of Perrigo's 30-count)
   - 40-count bottle and carton (representative of Perrigo's 50- and 100-count)

4. Instant Redeemable Coupon (IRC) Label
   - 160-count bottle (representative of Aleve® Liquid Gels 160-count)

The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable and should include Banner labels for all sizes covered in this supplement plus the Instant Redeemable Coupon that will be used.

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 (June 2008)." 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 021920/S-018**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Jade Pham, Regulatory Project Manager, at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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
04/01/2013