



NDA 021920/S-017

**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 December 15, 2011, received December 16, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for naproxen sodium capsule, 220 mg.

We acknowledge receipt of your amendment dated June 8, 2012.

We also acknowledge that the December 15, 2011, submission references the November 17, 2011, action letter to sNDA 021920, supplement 16.

This "Prior Approval" supplemental new drug application proposes the following labeling updates for naproxen sodium capsules, 220 mg, to better align with distributor labeling by Bayer Healthcare and Perrigo Pharmaceuticals:

1. Inclusion of the statement "Strength to Last 12 Hours" on the bottom left of the principal display panel (PDP)
2. Inclusion of the statement "Compare to the Active Ingredient of Aleve<sup>®</sup> Liquid Gels"

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.

We acknowledge that you do not market your product. However, we remind you that the distributors of your product must include an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture) in the tamper evident statement and also as part of the tamper-evident feature in accordance with 21 CFR 211.132(b)(1).

## **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 submitted December 15, 2011, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable:

### Modified Label Format

- 20-count immediate container (bottle) label
  - Representative of Perrigo’s 20-, and 30-count, and Bayer’s Aleve<sup>®</sup> Liquid Gels 20-count immediate container (bottle) label
- 20-count carton label
  - Representative of Aleve<sup>®</sup> Liquid Gels 20-count carton label
- 40-count immediate container (bottle) label
  - Representative of Perrigo’s 40-, 50-, 80-, 100-, and 160-count, and Aleve<sup>®</sup> Liquid Gels 40-count immediate container (bottle) label

### Standard Label Format

- 40-count carton label
  - Representative of Perrigo’s 20-, 30-, 40-, 50-, 80-, 100-, and 160-count, and Aleve<sup>®</sup> Liquid Gels 40-count carton label
- 160-count immediate container (bottle) label
  - Representative of Aleve<sup>®</sup> Liquid Gels 160-count carton label

### Non-Child Resistant Format

- 80-count non-child resistant immediate container (bottle) and carton label
  - Representative of Aleve<sup>®</sup> Liquid Gels 80-count immediate container (bottle) and carton label

FPL must be submitted for all representative count sizes. Representative labeling will not be acceptable in the FPL submission.

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-017.**” Approval of this submission by FDA is not required before the labeling is used.

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

Sincerely,

*{See appended electronic signature page}*

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

Enclosures: Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOEL SCHIFFENBAUER  
06/13/2012