DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-472/S-001

Banner Pharmacaps Incorporated
Attention; Donna Finch, R.Ph.
Director, Regulatory Affairs & Project Management
P.O. Box 2210
4125 Premier Drive
High Point, North Carolina 27261-2210

Dear Ms. Finch:

Please refer to your supplemental new drug application dated December 4, 2002, received December 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 200 mg ibuprofen capsules.

We acknowledge receipt of your submission dated July 22, 2003.

Your submission of July 22, 2003 constituted a complete response to our May 29, 2003 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for draft labeling for the outer carton and immediate container for 40-, 80-, 135- and 180-count packages.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the draft labeling submitted on July 22, 2003.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted on July 22, 2003), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-472/S-001". Approval of this submission by FDA is not required before the labeling is used.

We have the following additional recommendations for your consideration to be incorporated at the next printing:

Modify the carton labels so that bullets are presented in the same shape and 5-point size throughout the label, as follows.

a) On the 40-count carton label under the subheading "Stop use and ask a doctor if", adjust the bullet preceding "redness or swelling is present in the painful area".

b) On the 80-count carton, under "Uses", adjust the bullets preceding "headache", "muscular aches", and "minor pain of arthritis".

You are reminded that it is your responsibility as the NDA holder to ensure that your distributors' carton and container labels are identical in content to the labeling approved under your NDA, particularly regarding the "Drug Facts" labeling. We will not review and approve each of the individual distributor labels modeled on the template labels.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing NSAID's in the future.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

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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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Charles Ganley
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