DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-855

Banner Pharmacaps, Inc.
Attn: Shelly K. Meachum
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Ms. Meachum:

Please refer to your new drug application (NDA) dated October 1, 2004, received October 4, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for loperamide hydrochloride (1 mg and 2 mg soft gelatin) capsules.

We acknowledge receipt of your submissions dated November 05, December 13, 16, 2004, January 04, April 20, July 01, 11, 12, 20, 22, and August 02, 2005.

This new drug application provides for the use of Loperamide Hydrochloride Soft Gelatin Capsules, 1mg and 2mg, to control symptoms of diarrhea, including Travelers' Diarrhea.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (carton labels for the 6 and 72 count package sizes submitted July 22, 2005, and blister card labels for the 6 and 72 count package sizes submitted October 1, 2004), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-855.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for age birth to two years and note that you have fulfilled the remaining pediatric study requirements for this application.

We remind you of your postmarketing study commitment in your submission dated July 20, 2005. This commitment is listed below.

> You commit to evaluating the dissolution data for the 1 mg strength and set a final specification within one year of approval, based on the data. This specification change is for (b) (4) mg strength only, and the 2 mg strength dissolution specification will remain at Q = (b) (4) at 30 minutes.
>
> Study Start: Approval Date
> Final Report Submission: by August 2006

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Gastrointestinal and Coagulation Drug Products HFD-180 and the other copy, along with the labeling, to the Office of Nonprescription Products, HFD-560.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Oversight of this application is being transferred to the Office of Nonprescription Products.

If you have any questions, call Keith Olin, Regulatory Project Manager at (301) 827-2293.

Sincerely,

*{See appended electronic signature page}*

Curtis Rosebraugh, M.D., M.P.H.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

*{See appended electronic signature page}*

Brian E. Harvey, MD, PhD
Division Director
Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:


FPO
DIE 0075
FLAT SIZE 8.625 X 6.625
Drug Facts
Active Ingredient (in each capsule)
Purpose
Loperamide HCl 2mg
Anti-diarrheal
Use controls symptoms of diarrhea, including Travelers' Diarrhea
Warnings
Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl
Do not use ■ if you have bloody or black stool ■ in children under 12 years of age (see Other information)
Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease
Ask a doctor or pharmacist before use if you are taking antibiotics
When using this product drowsiness, dizziness, or dizziness may occur. Be careful when driving or operating machinery.
Stop use and ask a doctor if ■ symptoms get worse ■ diarrhea lasts for more than 2 days
■ you get abdominal swelling or bulging. These may be signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions
■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
■ not for use in children under 12 years of age
■ adults and children 12 years and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours
Other information
■ do not use if carton or blister unit is open or torn
■ avoid excessive heat above 40°C (104°F)
■ store at 20°-25°C (68°-77°F)
■ use the 1 mg soft gelatin capsule product for children 6 to under 12 years of age
■ see side panel for lot number and expiration date
Inactive ingredients butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water
Questions or comments? call toll free 1-800-447-1140
Manufactured by: Banner Pharmacaps Inc. 4125 Premier Drive High Point NC 27265
Lot #
Expiration Date
Rev # 7/05
Loperamide 2 mg Softgels*
NDC 00000-0000-00
Compare to the active ingredient in Imodium® A-D
Loperamide HCl
Soft Gelatin Capsules, 2 mg
Anti-Diarrheal
Suitable for adults and children 12 years and over
6 Softgels*
*each Liquid-filled capsule contains 2 mg loperamide HCl
FPO
0 00000 00000 0
BLACK