CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-429

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-429

NDA APPROVAL

Banner Pharmacaps, Inc.
Attention: Dana S. Toops
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27625

Dear Mr. Toops:

Please refer to your new drug application (NDA) dated July 31, 2008, received August 1, 2008 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for cetirizine HCl capsules, 5 mg and 10 mg.

We acknowledge receipt of your submissions dated September 8 and 25, October 29, and December 5, 2008 and February 9, April 14 and 22, May 12, 19 and 22, and June 26, 2009.

This new drug application provides for the nonprescription use of 5 mg and 10 mg cetirizine HCl capsules for the temporary relief of symptoms of runny nose, itchy, watery eyes, sneezing, and itching of the nose or throat due to hay fever or other upper respiratory allergies, and relief of itching due to hives.

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 (FPL) as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed carton and container labels submitted on May 20, 2009 for the 20 and 200 count 5 mg and 10 mg "allergy" and "hives relief" SKUs. The FPL must be must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The FPL 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 22-429**." Approval of this submission by FDA is not required before the labeling is used.

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.

We remind you of your concurrence to increase the size of the potency on the 5 mg and 10 mg carton and container distributor labels prior to the final printing of all the distributor carton and container labels to provide greater differentiation between the two different strengths.

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 note that you have fulfilled the pediatric study requirement for this application.

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

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
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
7/23/2009 09:13:36 AM