DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-152

NDA APPROVAL

Banner Pharmacaps Inc.
Attention: Dana S. Toops
Director, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Mr. Toops:

Please refer to your new drug application (NDA) dated September 20, 2006, received December 22, 2006, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Stavzor (valproic acid) Delayed Release Capsules, 125 mg, 250 mg, and 500mg.

We acknowledge receipt of your amendment dated May 27, 2008, which constituted a complete response to our December 21, 2007 action letter.

This new drug application provides for the use of Stavzor in the treatment of manic episodes associated with bipolar disorder, monotherapy and adjunctive therapy in multiple seizure types and prophylaxis of migraine headaches.

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 enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert,. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 22-152.”

We note your agreement, on July 29, 2008, to make the following changes to the Drug Listing Data Elements:

(1) Remove the "black imprinting ink" entry from the ingredient list.
(2) Revise "ammonium hydroxide" to "ammonia solution, strong".

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge that your May 27, 2008 submission contains final printed carton and container labels.

We note your agreement, on July 29, 2008, to revise your carton and container labels at the next printing (in September/October 2008) to delete or relocate the graphic circular "V" logo from immediately in front of the proprietary name.

Marketing the product with final printed labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Prophylaxis of Migraine Headache
We are waiving the pediatric study requirement for ages 12-17 years for this indication because a previous study in that age group failed to demonstrate effectiveness for this indication. We are waiving the pediatric study requirement for ages 6-11 years for this indication because, in light of the previous negative study in the 12-17 age group, it is not expected that valproate would be shown to be effective in patients with migraine in ages 6-11 years. In addition, the necessary studies are impossible or highly impracticable (the critical design elements for adequate studies in this age group for this drug for this indication are unknown) . We are waiving the pediatric study requirement for ages 0-5 years for this indication because the necessary studies are impossible or highly impracticable (migraine is difficult to diagnose in children under age 6 years and the critical design elements for adequate studies in this age group for this drug are unknown).

Acute treatment of manic episodes associated with bipolar disorder
We are waiving the pediatric study requirement for ages 10-17 years for this indication because a previous study in that age group failed to demonstrate effectiveness for this indication. In addition, we are waiving the pediatric study requirement for ages 0-9 years for this indication because the necessary studies are impossible or highly impracticable (this disease does not exist in children under age 10).

Treatment of simple & complex absence seizures
This product is appropriately labeled for use in ages birth up to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

Monotherapy and adjunctive therapy of complex partial seizures
We are waiving the pediatric study requirement for ages 0-9 years for this application because the necessary studies are impossible or highly impracticable (prior attempts of recruiting patients of that age group into a study have not been successful).

In addition, this product is appropriately labeled for use in ages 10 years up to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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 Jacqueline H. Ware, Pharm.D., RAC, Supervisory Regulatory Project Manager, at (301) 796-1160.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:
Stavzor FDA approved labeling text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

7/29/2008 03:29:51 PM