DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-152/S-001

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

Dear Ms. Toops:

Please refer to your supplemental new drug application dated August 1, 2008, received Augu4, 2008, submitted 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 500 mg.

This "Changes Being Effected" supplemental new drug application provides for the container closure information, supporting stability data and the labeling information for the 250 mg and 500 mg strengths of the physician sample bottles (10 count).

We completed our review of this supplemental new drug application and it is approved.

We remind you of your July 29, 2008, agreement to revise your carton and container labels at the next printing to delete or relocate the graphic circular "V" logo from immediately in front of proprietary name. We note that you also, in this supplement, committed to similarly revising your physician sample labeling at the next printing.

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

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Jim Vidra

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