DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22152/S-003 and S-004

SUPPLEMENT APPROVAL
REMS RETRACTION

Banner Pharmacaps Inc.
Attention: Vandana Garikipati, MS
Manager, Regulatory Affairs
4125 Premier Drive
High Point, NC 27265

Dear Ms. Garikipati:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	**Drug Product**	**Submitted on:**	**Received on:**	**Provides for:**
NDA 22152/S-003	Stavzor (valproic acid) Delayed Release Capsules	January 16, 2009	January 21, 2009	Proposed REMS including a Medication Guide.
NDA 22152/S-004	Stavzor (valproic acid) Delayed Release Capsules	October 13, 2011	October 13, 2011	Proposed Package Insert and Medication Guide that include pregnancy related changes requested by the Division via email correspondence on August 30, 2011 and September 9, 2011.

We acknowledge receipt of your amendments to S-003 dated April 16, 2009, August 19, 2009, April 7, 2010 and August 24, 2010.

We have completed our review of supplemental application S-004. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions, agreed upon in your January 14, 2013 email.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication

Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

In our letter dated December 16, 2008, we notified you that a risk evaluation and mitigation strategy (REMS) is required for Stavzor (valproic acid) to ensure that the benefits of the drug outweigh the increased risk of suicidal thoughts and behavior associated with the class of antiepileptic drugs (AEDs), of which Stavzor (valproic acid) is a member. We indicated that your REMS must include a Medication Guide and a timetable for submission of assessments of the REMS.

We acknowledge receipt of your proposed REMS as described in your January 21, 2009, April 17, 2009, April 8, 2010, and August 25, 2010 submissions. The proposed REMS, as amended, contains a Medication Guide and a timetable for submission of assessments of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the REMS to ensure that the benefits of Stavzor (valproic acid) outweigh its risks. Therefore, a REMS for Stavzor (valproic acid) is not required. We will notify you if we become aware of new safety information and make a determination that a REMS is necessary.

We remind you that the Medication Guide will be part of the approved labeling in accordance with 21 CFR 208.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Stacy Metz, PharmD, Regulatory Project Manager, at (301) 796-2139.

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(S):
Content of Labeling

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

/s/

RUSSELL G KATZ
02/26/2013