



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 8, 2013

**FILE COPY**

Samit Deb  
Sr. Director -Technical Operations  
Pharmaceutics International, Inc. (Pii)  
103 Beaver Ct.  
Cockeysville, MD 21030

Dear Mr. Deb:

Your petition to the Food and Drug Administration requesting a determination that Banner Pharmacaps discontinued its previously approved formulation of the Reference Listed Drug (RLD) STAVZOR® (valproic acid delayed release capsules) (Application Number 022152), for reasons unrelated to safety and effectiveness, was received by this office on 8/08/2013. It was assigned docket number FDA-2013-P-0948/CP1, and it was filed on 8/08/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an Agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Karen Kennard", is written above the typed name.

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)