



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 16, 2013

David B. Shirley, D.V.M.

exemption 6

FILE COPY

Dear Dr. Shirley:

Your petition to the Food and Drug Administration requesting the Agency to overturn the decision to rescind the Special Protocol Assessment for VASCEPA and to delay the PDUFA date for ANCHOR sNDA (sNDA 20257/S-005) was received by this office on 12/13/2013. It was assigned docket number FDA-2013-P-1612/CP12, and it was filed on 12/16/2013. 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,

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