



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 13, 2013

FILE COPY

Edith Hoechst
2285 North 163d Drive
Goodyear, AZ 85395

Dear Ms. Hoechst:

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 12/11/2013. It was assigned docket number FDA-2013-P-1612/CP7, and it was filed on 12/13/2013. 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 black ink, appearing to read "Karen Kennard", is written over the typed name and title.

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