



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 4, 2014

CORRECTED COPY

Erik Sacher
665 West Minister Road
Brooklyn, NY 11230

FILE COPY

Dear Mr. Sacher:

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 12/18/2013. It was assigned docket number FDA-2013-P-1612/CP18, and it was filed on 2/4/2014. 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 "D Bigby", is written over the word "Sincerely,".

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)