DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville MD 20857

FILE COPY

July 12, 2013

Jay S. Newman Fish & Richardson, P.C. 1425 K Street NW 11th Floor Washington, DC 20005

Dear Mr. Newman:

Your petition to the Food and Drug Administration on behalf of Spec Pharma, LLC, requesting to refrain from granting approval of the Beta Vet NADA until the arbitration panel determines Petitioner's and Applicant's ownership rights, was received by this office on 07/12/2013. It was assigned docket number FDA-2013-P-0862/CP1, and it was filed on 07/12/2013. 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,

Gloria Ortega

Administrative Proceedings Officer

Division of Dockets Management

FDA/Office of the Executive Secretariat (OES)