



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 22, 2013

FILE COPY

Paul W. Carr, P.E., R.A.C.
President
Shotwell & Carr, Inc.
1415 Halsey Way, Suite 304
Carrollton, TX 75007-4455

Dear Mr. Carr:

Your petition to the Food and Drug Administration requesting the FDA to make a determination that a new dosage form of cyclosporine oral solution for dogs (proposed trade name Cyclosporine 100 mg/mL Oral Solution) is suitable for submission as an ANADA, was received by this office on 04/22/2013. It was assigned docket number FDA-2013-P-0426/CP1, and it was filed on 04/22/2013. 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, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)