DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 25, 2013

Guy Rousseau Ph.D.
Executive Director, Regulatory Affairs
Aptalis Pharma US, Inc.
100 Somerset Corporate Boulevard
Bridgewater, NJ 0880

Dear Mr. Rousseau:

Your petition to the Food and Drug Administration requesting the Agency to refuse to receive or approve any ANDA for a generic version of Canasa unless and until such sponsor demonstrates bioequivalence in a clinical endpoint study, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1287/CP1, and it was filed on 10/25/2013. 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

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