



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 30, 2013

FILE COPY

Jennifer L. Bragg
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005-2111

Dear Ms. Bragg:

Your petition to the Food and Drug Administration requesting FDA to take actions requested in the petition with respect to any new drug application that seeks approval of an immunosuppressant indicated for maintenance therapy following renal transplantation, was received by this office on 04/30/2013. It was assigned docket number FDA-2013-P-0509/CP1, and it was filed on 04/30/2013. 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)