DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 18, 2013

FILE COPY

Augustine Frimpong, M.Sc.
Vice President, Regulatory Affairs I Compliance
Ascend Laboratories, LLC
180 Summit Avenue, Suite 200
Montvale, NJ 07645

Dear Mr. Frimpong:

Your petition to the Food and Drug Administration requesting to determine suitability Tacrolimus Oral Suspension as an additional dosage form to NDA 050708 PROGRAF (tacrolimus) capsule, gelatin coated and PROGRAF (tacrolimus) injection, solution held by Astellas Pharma US, Inc, was received by this office on 06/18/2013. It was assigned docket number FDA-2013-P-0767/CP1, and it was filed on 06/18/2013. 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)