DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 10, 2013

Leslie Sands
Director - Regulatory Affairs (USA)
Lupin Pharmaceuticals, Inc.
Harborplace Tower
111 South Calvert St., 21st Floor
Baltimore, MD 21202

Dear Ms. Sands:

Your petition to the Food and Drug Administration requesting FDA to determine whether BANZEL ® (rufinamide) Tablets, 100 mg was voluntarily withdrawn or discontinued from marketing for safety or effectiveness reasons as outlined in the petition, was received by this office on 05/10/2013. It was assigned docket number FDA-2013-P-0573/CP1, and it was filed on 05/10/2013. 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)