DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 3, 2013

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

Dear Ms. Sands:

Your petition to the Food and Drug Administration requesting FDA to amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book") to assign a second reference – listed drug product for Calcium Acetate Capsules, was received by this office on 1/3/2013. It was assigned docket number FDA-2013-P-0040/CP1, and it was filed on 1/3/2013. 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)

FDA-2013-P-0040

ACK