DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

July 11, 2013

Michael H. Hinckle
K&L GATES LLP
Post Office Box 14210
Research Triangle Park, NC 27709-4210

Dear Mr. Hinckle:

Your petition to the Food and Drug Administration requesting on behalf of client to establish the in vivo bioequivalence of its proposed generic drug product and the KUVAN drug product with bioequivalence studies using the KUVAN drug product obtained in Israel as the reference product based on evidence that the KUVAN drug product marketed in Israel is the same, in all material respects, as the KUVAN product described in the applicable approved New Drug Application ("NDA"), was received by this office on 07/11/2013. It was assigned docket number FDA-2013-P-0846/CP1, and it was filed on 07/11/2013. 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)