DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JAN 6 2014

Michael H. Hinckle
K&L Gates LLP
P.O. Box 14210
Research Triangle Park, NC 27709-4210

Re: Docket No. FDA-2013-P-0846

Dear Mr. Hinckle:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on July 11, 2013. Your petition requests that your client (a manufacturer planning to submit an abbreviated new drug application for KUVAN (sapropterin dihydrochloride) 100 mg tablets) be permitted to demonstrate bioequivalence using supplies of KUVAN marketed in Israel rather than the US-approved reference listed drug (Petition at 1).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research