DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-181/S-001

BioMarin Pharmaceuticals Inc.
Attention: Ruhi Ahmed, Associate Director, Regulatory Affairs
105 Digital Drive
Novato, CA 94949

Dear Mr. Ahmed:

Please refer to your supplemental new drug application dated December 19, 2007, received December 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kuvan (sapropterin dihydrochloride) Tablets, 100 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional bottle size, i.e., a new 30- count container/closure configuration.

We completed our review of this supplemental new drug application and it is approved. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1) in structured product labeling (SPL) format submitted on December 20, 2007

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel

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