DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-959/S-003

Medicis Pediatrics, Inc.
c/o BioMarin Pharmaceutical Inc.
Attention: Ruhi Ahmed, Ph.D., RAC, Ass. Director, BioMarin Pharmaceutical Inc.
105 Digital Drive
Novato, CA 94949

Dear Dr. Ahmed:

Please refer to your supplemental new drug application dated October 24, 2008, received October 27, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Orapred ODT™ (prednisolone sodium phosphate) Tablets.

We acknowledge receipt of your submission dated April 2, 2009.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional packaging configuration of 14-tablet card pack and an alternate secondary packaging facility (b) (4) for the drug product.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

- Please refer to your package insert submitted April 2, 2009. Under description section, the inactive ingredient, "grape flavor" is replaced with .
  We acknowledge your email correspondence dated April 24, 2009 informing the replacement as an inadvertent error.
  Submit a corrected version of package insert in SPL format to accurately identify "grape flavor" as one of the inactive ingredient.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed. These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 21-959/S-003."

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jim Vidra

4/27/2009 04:03:56 PM