CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-959

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-959

BioMarin Pharmaceutical Inc.
105 Digital Drive
Novato, CA 94949

Attention: Ruhi Ahmed, Ph.D., RAC
Manager, Regulatory Affairs

Dear Dr. Ahmed:

Please refer to your new drug application (NDA) dated July 28, 2005, received August 1, 2005, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ORAPRED ODT (prednisolone sodium phosphate orally disintegrating tablets),10 mg, 15 mg, and 30 mg Tablets.

We acknowledge receipt of your submissions dated February 10, April 6 and 25, and May 12, 22, 26, and 31, 2006.

This new drug application provides for the use of **ORAPRED ODT** for various indications related to **Allergic States, Dermatologic Diseases, Edematous States, Endocrine Disorders, Gastrointestinal Diseases, Hematologic Disorders, Neoplastic Diseases, Nervous System, Ophthalmic Diseases, Respiratory Diseases, Rheumatic Disorders,** and other **Miscellaneous** indications listed in the enclosed labeling.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert submitted May 31, 2006, and immediate container and carton labels, submitted May 26, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-959**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. Your pediatric studies are waived because formulations already marketed permit flexibility on dosing across the dosage range recommended for prednisolone in the pediatric population.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

If you have any questions, call Parinda Jani, Chief, Project Management Staff, at (301) 796-1232.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport
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