DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125058/220

SUPPLEMENT APPROVAL

BioMarin Pharmaceutical Inc.
Attention: Ben Dewees
Associate Director, Regulatory Affairs
105 Digital Drive
Novato, CA 94949

Dear Mr. Dewees:

Please refer to your Supplemental Biologics License Application (sBLA) dated January 13, 2012, received January 17, 2012, submitted under section 351(a) of the Public Health Service Act for Aldurazyme (laronidase).

We acknowledge receipt of your amendment dated September 6, 2012.

This "Prior Approval" supplemental biologics application provides for changes to the following sections of the package insert:

- Dosage and Administration - add instruction for use of in-line, low-protein-binding 0.2 μm filter (2.2)
- Adverse Reactions - clarify language in Immunogenicity (6.2); add laryngeal edema, fatigue, and edema peripheral to Postmarketing Experience (6.3)
- Clinical Pharmacology – add pharmacokinetics data from Postmarketing Requirement (PMR) #1 to Pharmacokinetics (12.3) as requested in the fulfillment letter issued on September 11, 2011

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling

Technical Qs and As" at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

JOYCE A KORVICK
04/03/2013