



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125058/154

BioMarin Pharmaceutical Inc.
Attention: Jeri Beltman, Ph.D.
Manager, Regulatory Affairs
105 Digital Drive
Novato, CA 94949

Dear Dr. Beltman:

Your request to supplement your biologics license application for Aldurazyme (laronidase) to update the product package insert with safety information has been approved.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125058/154." In addition, within 21 days of the date of this letter, amend any pending supplements for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

Daniel Shames, M.D.
Deputy Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Rx Only

ALDURAZYME is manufactured by:

BioMarin Pharmaceutical Inc.

105 Digital Drive

Novato, CA 94949

US License Number 1649

ALDURAZYME is distributed by:

Genzyme Corporation

500 Kendall Street

Cambridge, MA 02142

1-800-745-4447 (phone)

ALDURAZYME is a registered trademark of BioMarin/Genzyme LLC.

5649(03/08) (FDA Revised 1/2008)