DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125151/32

Shire Human Genetic Therapies, Inc.
Attention: Howard Yuwen, Ph.D.
Senior Director, Regulatory Affairs
700 Main Street
Cambridge, MA 02139

Dear Dr. Yuwen:

Your request to supplement your biologics license application for Elaprase to update the boxed warning and Warnings section regarding two events of late-emergent anaphylactiod reactions has been approved.

We note your October 11, 2007, submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 days of the date of this letter, amend any pending supplement(s) 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,

10/24/07

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