DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Office of Technology
Transfer
National Institutes of Health
6011 Executive Boulevard
Rockville, MD 20852

October 22, 2010

Ms. Amber Britton
13212 NE 138th PI
Kirkland, Washington 98034

Dear Ms. Britton:

Thank you for your September 27, 2010 letter, which provides us with important information on the seriousness of the Fabry disease that is complicated by your inability to obtain the correct dosage of Fabrazyme.

NIH received from Dr. Allen Black, on behalf of clients whose supply of the drug has been rationed, a request to initiate march-in proceedings with the goal to increase the production and patient access to the drug Fabrazyme. The technology is based on an invention made by Mount Sinai Hospital scientists under an NIH grant and subsequently licensed exclusively to Genzyme Corporation. A march-in proceeding could result in the granting of an open, nonexclusive license to the patented invention such that other companies would have the right to use the patent to manufacture it. A march-in proceeding will not, however, have any affect on a competing supplier's ability to manufacture, clinically test, and obtain regulatory approval for its version of the drug.

NIH is concerned about the welfare of all patients that suffer from Fabry disease. We want to assure you that NIH is working on this issue as quickly as it can and will issue its decision as soon as possible within the confines of the regulations governing this action (37 C.F.R. § 401.6).

Sincerely,

Mark L. Rohrbaugh, Ph.D., J.D.
Director
Office of Technology Transfer

MLR:sf