



Food and Drug Administration
Rockville MD 20857

6640 '04 MAR -1 09:38

Re: Fabrazyme
Docket No.: 03E-0406

FEB 25 2004

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,356,804, filed by Genzyme, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Fabrazyme, the human biological product claimed by the patent.

The total length of the regulatory review period for Fabrazyme is 1,843 days. Of this time, 807 days occurred during the testing phase and 1,036 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biological product became effective: April 9, 1998.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 9, 1998.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: June 23, 2000.

FDA has verified the applicant's claim that the product license application (PLA) for Fabrazyme (PLA 103979/0) was initially submitted on June 23, 2000.

3. The date the application was approved: April 24, 2003.

FDA has verified the applicant's claim that PLA 103979/0 was approved on April 24, 2003.

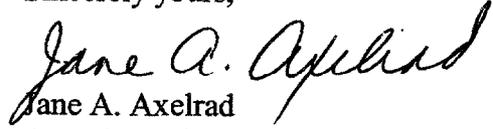
03E-0406

LET 4

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Anthony Insogna
Pennie & Edmonds
1155 Avenue of the Americas
New York, NY 10036-2711