



David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

4 3 2 0 '04 JAN 12 P 1 53

DEC 8 2003

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,356,804. The application was filed on June 20, 2003, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, and a method for making such a product. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Anthony M. Insogna
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RE: FABRAZYME® (agalsidase beta)
Docket No. 03E-0406

03E-0406

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