



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

DEC 8 2003
JAN 12 2004

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Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,382,518. The application was filed on September 9, 2002, 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. 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

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

cc: Michael D. Alexander
Sanofi-Synthelabo Inc.
9 Great Valley Parkway
Malvern PA 19355

RE: ELITEK® (rasburicase)
Docket No. 03E-0249

03E - 0249

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