



UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

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

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,196,404, was filed on February 14, 2001, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Angiomax™ (bivalirudin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. In addition, the assistance of your Office is requested in confirming that the application for patent term extension was **NOT** filed within sixty days after the product was approved.

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is not to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would **NOT** be eligible for extension of the patent term under 35 U.S.C. § 156. The approval letter and the application for patent term extension indicates that the product was approved on December 15, 2000. Sixty days after this date is February 13, 2001, before the date the application was filed, i.e., February 14, 2001. As a result, the application appears to have been filed late, and that the application must be dismissed as having been filed outside of the statutory period. The statutory time period is not extendable and cannot be waived or excused. See the file history of U.S. Patent No. 4,486,425 (application for patent term extension filed after the end of the 60-day period and was therefore denied).

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

cc: Paul Granger, Esq.
The Medicines Company
One Cambridge Center
Cambridge MA 02142

OIE-0213

LETI

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Drug Approvals for December 2000

Definitions and Notes

Original New Drug Applications

Original Application #: 021228

Approval Date: 22-DEC-00

Trade Name: DETROL LA

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: CAPSULE

Applicant: PHARMACIA AND UPJOHN CO

Active Ingredient(s): TOLTERODINE TARTRATE

OTC/RX Status: RX

Indication(s): For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency

Original Application #: 020873

Approval Date: 15-DEC-00

Trade Name: ANGIOMAX

Chemical Type: 1 = *new chemical entity*

Therapeutic Potential: S

Dosage Form: INJECTABLE

Applicant: MEDICINES CO (TMC)

Active Ingredient(s): BIVALIRUDIN

OTC/RX Status: RX

Indication(s): As an anticoagulant in conjunction with aspirin in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA)

Original Application #: 050777

Approval Date: 08-DEC-00

Trade Name: PROTOPIC

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: OINTMENT

Applicant: FUJISAWA HEALTHCARE INC

Active Ingredient(s): TACROLIMUS

OTC/RX Status: RX

Indication(s): For short term and intermittent, long term therapy in the treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or intolerant of alternative, conventional therapies