



Food and Drug Administration
Rockville MD 20857

NOV 2 2006

Re: Angiomax
Docket No. 01E-0213

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the March 24, 2003, letter from Karin Ferriter requesting FDA's assistance in preparing a response to a request for reconsideration in the application for patent term extension for U.S. Patent No. 5,196,404 filed by The Medicine Company under 35 U.S.C. § 156. The human drug product claimed by the patent is Angiomax (bivalirudin), which was assigned new drug application (NDA) No. 20-873.

The applicant argues that the approval date for NDA 20-873 should be December 18, 2000, not December 15, 2000 (a Friday), because the approval letter was signed after FDA's normal business hours on December 15.

The FDA reiterates that NDA 20-873 for Angiomax was approved on December 15, 2000.

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

Sincerely yours,

A handwritten signature in cursive script that reads "Jane A. Axelrad".

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

Patent Term Extension
Angiomax Patent # 5,196,404
Page 2

cc: Hollie Baker
Wilmer, Cutler, Pickering, Hale and Dorr, LLP
60 State Street
Boston, MA 02109

Paul Antinori
The Medicine Company
8 Campus Drive
Parsippany, NJ 07054