DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-873/S-009

The Medicines Company
Attention: Sonja Loar, Pharm. D.
200 Fifth Avenue
Waltham, MA 02451

Dear Dr. Loar:

Please refer to your supplemental new drug application dated November 12, 2003, received November 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Angiomax® (bivalirudin) for Injection.

We acknowledge receipt of your submission dated February 17, 2004.

Your submission of February 17, 2004 constituted a complete response to our February 10, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides revisions to the PRECAUTIONS and ADVERSE EVENTS sections of the package insert to include information regarding the use of Angiomax in patients undergoing percutaneous intracoronary brachytherapy.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the labeling text for the package insert, submitted February 17, 2004.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-873/S-009." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to

the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alice Kacuba, Regulatory Health Project Manager, at (301) 827-9334.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
5/7/04 12:28:20 PM
for Dr. Robert Justice