**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-873/SLR-014

The Medicines Company
Attention: Gary Knappenberger
8 Campus Drive
Parsippany, NJ 07054

Dear Mr. Knappenberger:

Please refer to your supplemental new drug application dated March 2, 2005, received March 3, 2005, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Angiomax® (bivalirudin) for Injection.

This "Changes Being Effected" supplemental new drug application provides for the following: 1) revisions to the ADVERSE REACTIONS section of the package insert to include events reported in postmarketing safety surveillance and 2) revision to the DOSAGE AND ADMINISTRATION section of the package insert to add compatibility information obtained from the literature regarding a potential incompatibility between Angiomax and dobutamine.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 2, 2005.

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) 301-827-9334.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation

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

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/s/
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Kathy Robie-Suh
9/2/2005 04:26:09 PM
signing for Dr. Joyce Korvick