DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-873/S-004

The Medicines Company
Attention: Sonya Loar, Pharm.D.
Senior Director, Regulatory Affairs
One Cambridge Center
Cambridge, MA 02142

Dear Dr. Loar:

Please refer to your supplemental new drug application dated June 8, 2001, received June 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Angiomax (bivalirudin) Injection.

We acknowledge receipt of your submissions dated February 6, and June 7, 2002. Your submission of February 6, 2002 constituted a complete response to our December 20, 2001 action letter.

This "Changes Being Effected" supplemental new drug application provides for revising the DOSAGE AND ADMINISTRATION section, “Instructions for Administration” subsection of the package insert to include information obtained from the results of a physical compatibility screening study of Angiomax and 96 selected medications during a Y-site administration.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling text agreed to in the June 7, 2002 facsimiles.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten 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-004." Approval of this submission by FDA is not required before the labeling is used.

In addition, consider conducting a study to demonstrate that the drugs tested for compatibility do not cause chemical degradation of the active ingredient, bivalirudin, under the labeled administration conditions.

Please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alice Kacuba, R.N., MSN, RAC, Regulatory Health project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and 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
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