DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-873/S-023 **SUPPLEMENT APPROVAL**

The Medicine Company
Attention: Gary D. Knappenberger
Senior Director, Global Regulatory Operations
8 Sylvan Way
Parsippany, NJ 07054

Dear Mr. Knappenberger:

Please refer to your Supplemental New Drug Application (sNDA) dated December 23, 2009, received December 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Angiomax® (bivalirudin) injection.

We acknowledge receipt of your submission dated March 3, 2010.

This "Prior Approval" supplemental new drug application revises your currently approved Packet Insert (PI) label, in the old format, into the new Physician Labeling Rule (PLR) format.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

**REPORTING REQUIREMENTS**

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 Ebla Ali Ibrahim, Regulatory Project Manager, at (301) 796-3691.

Sincerely,

*{See appended electronic signature page}*

Ann Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Package Insert

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-20873 | SUPPL-23 | THE MEDICINES CO | ANGIOMAX |

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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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ANN T FARRELL
06/23/2010