DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-884/S-014

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Dr. Daniel Coleman
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Dr. Coleman:

Please refer to your supplemental new drug application dated June 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrenox (aspirin/extended-release dipyridamole) 25/200 mg Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the **ADVERSE REACTIONS, Other Adverse Events,** *Skin and Appendages Disorders* section of the label, as well as minor editorial revisions throughout the labeling.

We have 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 electronically submitted content of labeling [21 CFR 314.50(l)] in structured product labeling format (content of labeling submitted June 15, 2006.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call:

Meg Pease-Fye, M.S.
Regulatory Project Manager
(301) 796-1130

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal
Products Office of Drug Evaluation I Center
for Drug Evaluation and Research

Enclosure: approved labeling

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

/s/

Norman Stockbridge

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