



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-884/S-012

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 originally submitted January 26, 2006, received March 2, 2006 (date removed from Arrears List), and resubmitted February 23, 2007, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrenox (aspirin/extended-release dipyridamole) 25/200 mg Capsules.

This supplemental NDA proposed changes to the **DOSAGE AND ADMINISTRATION** section of the package insert. Your submission of February 23, 2007 constituted a complete response to our January 3, 2007 approvable letter.

We have completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on February 23, 2007.

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

Attached:  
Final Printed Labeling

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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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Norman Stockbridge  
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