DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-884/S-018 **SUPPLEMENT APPROVAL**

Boehringer-Ingelheim
Attention: David R. Brill, Ph.D.
Director, Drug Regulatory Affairs
900 Ridgebury Rd.
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Dr. Brill:

Please refer to your supplemental new drug application (sNDA) dated December 1, 2009, received December 2, 2009, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aggrenox (aspirin/extended release dipyridamole) 25 mg/200 mg Capsules.

We acknowledge receipt of your submissions dated January 20 and 27, March 5, and September 21, 2009.

We have completed our review of this 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, please submit 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 text for the patient package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 20-884/S-018**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, please call:

Alison Blaus
Regulatory Health Project Manager
301-796-1138

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: Final Product Labeling
Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20884	SUPPL-18	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	AGGRENOX

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

/s/

NORMAN L STOCKBRIDGE
10/01/2009