DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-884/S-007

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ms. Tacy Pack
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Pack:

Please refer to your supplemental new drug application dated February 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrenox (aspirin/extended-release dipyridamole) 25/200 mg Capsules.

We acknowledge receipt of your submissions dated December 31, 2002; and September 26 and November 11, 2003.

Your electronic submission of September 26, 2003 constituted a complete response to our December 19, 2002 action letter.

This supplemental new drug application provides for revisions in the **DESCRIPTION, WARNINGS, PRECAUTIONS, Carcinogenesis, Mutagenesis, Impairment of Fertility, PRECAUTIONS, Pregnancy**, **PRECAUTIONS/Nursing Mothers** subsections.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 26, 2003.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

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

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, HFD-410
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 Meg Pease-Fye, Regulatory Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton
Director,
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I

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

/s/

Doug Throckmorton
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