DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-884/S-003

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Cornelius M. Dunn
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877-0368

Dear Mr. Dunn:

Please refer to your supplemental new drug application dated October 20, 2000, received October 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aggrenox (aspirin/extended-release dipyridamole) Capsules, 25 mg/200 mg.

This "Changes Being Effected" supplemental new drug application provides for the replacement of the currently approved container closure system with a new container closure system incorporating a child resistant closure.

We have completed the review of this supplemental application and it is approved.

Please note that the final printed labeling for the package insert, which included changes to sections other than "How Supplied" and "Description," has not been reviewed in conjunction with this supplemental application. We consider this labeling to be the final printed labeling we requested in our July 27, 2000 approvable letter to your March 28, 2000 supplemental application (S-001). A separate action letter will be issued for these labeling updates.

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 Colleen LoCicero, Regulatory Health Project Manager, at (301) 594-5332.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
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