



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-836/S-057

Boehringer Ingelheim Pharmaceuticals Inc.
Attention: Kelly S. Billingham
Manager, Product Labeling
900 Ridgebury Road
P.O. Box 368
Ridgefield, Co 06877-0368

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated February 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Persantine (dipyridamole USP) 25, 50 and 75 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following revision to the package insert:

Under the **ADVERSE REACTIONS** section, a second sentence has been added to the end of the third paragraph. The entire paragraph now reads, "When Persantine tablets were administered concomitantly with warfarin, bleeding was no greater in frequency or severity than that observed when warfarin was administered alone. In rare cases, increased bleeding during or after surgery has been observed."

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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, please call Ms. Meg Pease-Fye, M.S., Regulatory Project Manager, at (301) 594-5327.

Sincerely,

{See appended electronic signature page}

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

Attached:
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
8/1/05 10:31:39 AM