



NDA 20-757/S-037

Sanofi-Aventis
c/o Bristol-Myers Squibb Company
Attention: Grace D. Heckman
Director, Cardiovascular Products
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Ms. Heckman:

Please refer to your supplemental new drug application dated 29 June 2005, received 30 June 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro® (irbesartan) 75, 150, and 300 mg Tablets.

Your submission of 29 June 2005 constituted a complete response to our 7 October 2002 supplement request letter.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for final printed labeling revised as follows:

1. Under **Post-Marketing Experience**, the following statement has been added:

"Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers."

2. Under **Geriatric Use**, the last statement was revised as follows:

From: (See **Pharmacokinetics, Special Populations, and Clinical Studies.**)

To: (See **CLINICAL PHARMACOLOGY: Pharmacokinetics, Special Populations, and Clinical Studies.**)

3. Minor administrative changes were noted as follows:

- Percent was replaced with %
- Part number was revised
- Date was revised

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on 29 June 2005.

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:

Cheryl Ann Borden, MSN, RN, CCRN, CCNS
Regulatory Health Project Manager
(301) 796 1046.

Sincerely,
{See appended electronic signature page}
Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardiovascular and Renal Drug
Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Norman Stockbridge
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