DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-038

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

Dear Mr. Silberstein:

Please refer to your supplemental new drug application for NDA 20-757 dated 27 October 2005, received 28 October 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 27 October 2005 constituted a complete response to our 8 February 2005 supplement request letter.

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

1. Under **ADVERSE REACTIONS, Post-Marketing Experience**, hepatitis was added to the first paragraph.

2. Minor administrative changes were noted as follows:
    - Under CLINICAL PHARMACOLOGY:
        - Special Populations, Gender: gender related was changed to gender-related.
        - Pharmacodynamics, the second paragraph:
            - 1.5-2fold was changed to 1.5- to 2-fold.
            - 2-3-fold was changed to 2- to 3-fold.
        - Nephropathy in Type 2 Diabetic Patients, in the fourth paragraph: end point was changed to end-point.
    - Part number was revised
    - Date was updated to October 2005

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 27 October 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.
Director
Division of Cardiovascular and Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Sanofi-Synthelabo
Attention: Ms. Colleen Davenport, Ph.D.
Associate Director, Regulatory Affairs
9 Great Valley Pkwy
Bldg 31 131L
Malverne, PA 19355

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

4/21/2006 06:00:36 PM