**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-758/S-036

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 20-758 dated 27 October 2005, received 28 October 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avalide® (irbesartan-hydrochlorothiazide) 150/12.5, 300/12.5, and 300/25 mg Tablets.

Your submission of 27 October 2005 was in 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, Pediatrics: Irbesartan was replaced with Irbesartan-hydrochlorothiazide.
    - Percent was replaced with %
    - Blood brain was replaced with blood-brain
    - Isozymes was replaced with isoenzymes
    - (oral agents and insulin) was changed to (*oral agents and insulin)*
    - "And" was replaced with "and"
    - Tablets was added after AVALIDE in the *Non-steroidal Anti-Inflammatory Drug* section
    - *in vitro* human was revised to *in vitro*-human
    - *in vivo* mouse was revised to *in vivo*-mouse
    - Under ADVERSE REACTION, Irbesartan-hydrochlorothiazide was revised with Irbesartan-Hydrochlorothiazide
    - Regional Poison Control Center was revised to regional Poison Control Center
    - poison control centers was revised to Poison Control Center
    - 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

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

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/s/

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Norman Stockbridge

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