



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-758/S-035

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 20 May 2005, received 24 May 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 20 May 2005 constituted a complete response to our 7 October 2002 supplement request letter.

This "Changes Being Effected 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. Minor administrative changes were noted as follows:

- Under **DESCRIPTION**: the chemical name was rewritten to reflect commas or hyphens in place of spaces
- Under **Lithium Interaction**: semi colons were replaced with colons.
- **Information For Patients** was revised to **Information for Patients**
- Under **ADVERSE REACTIONS, Hydrochlorothiazide**:
  - *Body AS A Whole* was revised to *Body as a Whole*
- Under **HOW SUPPLIED**: parenthesis were added before and after debossed numbering
- 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 20 May 2004.

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/

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Norman Stockbridge  
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