



NDA 20-758/S-037

Sanofi-Aventis  
c/o Bristol-Myers Squibb Company  
Attention: Nic Scalfarotto, D.V.M.  
P.O. Box 4000 (Mailstop D32-01)  
Princeton, NJ 08543-4000

Dear Dr. Scalfarotto:

Please refer to your supplemental new drug application dated December 15, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avalide (irbesartan/hydrochlorothiazide) 150-12.5 mg, 300-12.5 mg, and 300-25 mg Tablets.

We acknowledge receipt of your submissions dated October 24, November 2, 21, 27, December 13, 19, 2006, and February 15, 16, 21, 23, 27, March 1, 14, 30, April 9, May 8, 17, June 15, July 5, 10, 27, August 3, 29, September 13, and October 16, 29, 2007.

Your submission of October 29, 2007 constituted a complete response to our October 13, 2006 approvable letter.

This supplemental new drug application provides for revised labeling to permit use of Avalide (irbesartan/hydrochlorothiazide) Tablets as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate the submission as "**FPL for approved supplement NDA 20-758/S-037.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing commitment between yourself and Dr. Norman Stockbridge of the Division of Cardiovascular and Renal Products agreed upon during the November 15, 2007 teleconference. This commitment is listed below.

1. You agree to perform a database search and reanalysis of the adverse reaction data for Avalide and, if needed, submit a labeling supplement to the FDA by 5/16/09 to update the appropriate sections of the labeling accordingly.

Under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final submission dates, and any changes in plans since the last annual report. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled “**Postmarketing Commitment Correspondence.**”

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.  
Regulatory Project Manager  
(301) 796-0510

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Agreed-upon labeling text

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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  
11/16/2007 05:30:31 PM