



NDA 20-757/S-021

Sanofi-Synthelabo Inc.
Attention: Dr. Richard Gural & Ms. Grace D. Heckman
90 Park Avenue
New York, NY 10016

Dear Dr. Gural and Ms. Heckman:

Please refer to your supplemental new drug application dated August 3, 2001, withdrawn January 31, 2002 and resubmitted on March 22, 2002 (our receipt date, March 25, 2002). This application was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) Tablets, 75, 150 and 300 mg.

We acknowledge receipt of your submissions dated June 10 and 17, July 22, 25, and 26, August 9 and 29, and September 5, 2002. Your submission of September 5, 2002 constituted a complete response to our June 6, 2002 approvable letter.

This supplemental new drug application provides for the use of Avapro (irbesartan) Tablets, 75, 150 and 300 mg for the treatment of type 2 diabetic nephropathy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted electronic final printed labeling (package insert included in your submission of September 05, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We acknowledge your requests of August 3, 2001 and July 22, 2002 asking for a waiver of the pediatric study requirement for this new indication. We agree to waive the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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 contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosed Labeling Text

cc:
Bristol-Myers Squibb
Attention: Ms. Grace D. Heckman
P.O. Box 4000
Princeton, NJ 08543-4000

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

/s/

Robert Temple
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