CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 20-757/S-021

Approvable Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-757/S-021

Sanofi-Synthelabo Inc.
Attention: Dr. Richard Gural
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Please refer to your supplemental new drug application dated August 3, 2001, withdrawn January 31, 2002 and resubmitted on March 25, 2002 (our receipt of your March 22, 2002 submission). 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 March 22, April 3, 4 and 29, and May 17, 2002.

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

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The FPL should be identical in content to the enclosed draft labeling (text for the package insert).

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL, ten of which individually mounted on heavy weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it

is marketed with these changes prior to approval of this supplemental application.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

23 pages redacted from this section of the approval package consisted of draft labeling

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
6/6/02 07:17:21 PM