**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757 / S-022

Sanofi-Synthelabo, Inc.
Attention: David Ziering, Ph.D.
90 Park Avenue
New York, NY 10016

Dear Dr. Ziering:

Please refer to your supplemental new drug application dated January 24, 2002, received January 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro, (irbesartan) Tablets 75 mg, 150mg and 300mg.

We acknowledge receipt of your submission dated July 18, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for Sanofi Winthrop Industrie, Ambares, France as an alternative drug product manufacturing and release testing site.

We have completed our review of this application, as amended and it is approved. Please provide final printed labeling (FPL) in your next annual report.

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, call Edward Fromm, Regulatory Project Manager, at (301) 594-5300.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph. D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

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Kasturi Srinivasachar

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