DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JAN 29 1998

H. Oliver Stoutland, MD
Director, Promotional Compliance
Bristol-Myers Squibb Corporation
777 Scudders Mill Road
Plainsboro, NJ 08536

RE: **NDA 20-757**
Avapro (irbesartan) Tablets
MACMIS ID # 5969

Dear Dr. Stoutland:

Reference is made to Bristol-Myers Squibb Company's (BMS) letter, dated January 7, 1998, in response to a letter from the Division of Drug Marketing, Advertising and Communications (DDMAC), dated December 23, 1997. DDMAC's letter concerned the alleged dissemination of a homemade promotional piece (birth announcement) by or on behalf of BMS, that promoted Avapro (irbesartan) tablets in violation of the Federal Food, Drug and Cosmetic Act (Act) and its regulations. DDMAC requested that BMS investigate the extent to which this homemade piece was used to promote Avapro, and the number of health care professionals who received this piece.

In your letter, you described that this homemade promotional birth announcement was distributed by three sales representatives to approximately 36 physicians at 12 locations in the Alexandria and St. Charles, Louisiana area. Your letter also described BMS' policy for prohibiting dissemination of homemade materials by your sales force, and specified the corrective actions taken to ensure that this activity will not continue.

DDMAC has reviewed this promotional birth announcement and has determined that it is lacking in fair balance with respect to the content and presentation of risk information related to the use of Avapro. Promotional materials must present information about the risks associated with the use of the drug in a manner reasonably comparable to that of claims concerning the drug's efficacy. However, this promotional piece does not contain any information about the risks, warnings, precautions, or adverse events associated with Avapro's use.

In addition, the approved product labeling for Avapro contains a boxed warning concerning its use in pregnancy, which is not presented in this promotional piece. Moreover, the format of this promotional piece, as a birth announcement, may suggest that the use of Avapro is appropriate during pregnancy. Due to the risk of fetal injury or death, this use would clearly be contraindicated. Therefore, since Avapro has significant risks associated with its use, especially

during pregnancy, this promotional piece is lacking in fair balance, or otherwise misleading because it fails to address these risks.

Lastly, the promotional birth announcement is in violation of the Act because it was not accompanied by the approved product labeling for Avapro.

DDMAC has reviewed your response and actions taken in response to the dissemination of this violative promotional piece. DDMAC does not wish to comment on the internal processes of BMS, however we do acknowledge BMS' investigation and the corrective actions taken to prevent reoccurrence of this type of violative promotional activity. At this time, DDMAC has no further questions and considers this matter closed.

If you have any further questions or comments, please direct them to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds BMS that only written communications are considered official.

In all future correspondence regarding this particular matter please refer to MACMIS ID #5969 in addition to the NDA number.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

cc: Gregory Torre, Ph.D., J.D.
Senior Director, Drug Regulatory Affairs
Sanofi Pharmaceuticals, Inc.
90 Park Avenue
New York, NY 10016