DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Ms. Catherine K. Clark
Director, US Regulatory Affairs
SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road, PO Box 5089
Collegeville, PA 19426-0989

OCT 15 1997

RE: NDA# 20-297
Coreg (carvedilol) Tablets
MACMIS ID #5899

Dear Ms. Clark:

Reference is made to a journal ad (CO4671) submitted by SmithKline Beecham Pharmaceuticals (SmithKline) under cover of Form FDA 2253, dated June 27, 1997, to the Division of Drug Marketing, Advertising and Communications (DDMAC). DDMAC has reviewed this promotional material and determined that it promotes Coreg (carvedilol) tablets in a manner in violation of the Federal Food, Drug and Cosmetic Act and its regulations. Specifically, it is lacking in fair balance or otherwise misleading.

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. This journal ad fails to present any information relating to the most common adverse events, warnings, or precautions associated with Coreg. Therefore, this journal ad is lacking in fair balance or otherwise misleading because it fails to address risks associated with Coreg's use.

On July 31, 1997, Catherine Clark of SmithKline notified DDMAC that the above referenced journal ad had mistakenly been released without fair balance information. Ms. Clark also stated that distribution of the journal ad had ceased. DDMAC requested that SmithKline write a letter to DDMAC confirming that the violative journal ad was no longer in use.

At this time, DDMAC has not received confirmation that this journal ad is no longer in use for promotion of Coreg. Therefore, SmithKline should submit a written response to DDMAC on or before October 29, 1997, confirming that SmithKline has ceased distribution of the above referenced journal ad, and any other promotional materials containing the same or similar claims or presentations.

SmithKline should direct its response 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 SmithKline that only written communications are considered official.

In all future correspondence regarding this particular issue, please refer to MACMIS ID #5899 in addition to the NDA number.

Sincerely,

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