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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

FEB - 9 1999

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

RE: NDA# 20-297
Coreg (carvedilol) Tablets
MACMIS ID #7559

Dear Ms. Clark:

Reference is made to a journal advertisement (CO 0308) for Coreg (carvedilol) tablets, disseminated by SmithKline Beecham Pharmaceuticals (SB). This advertisement was published in *The Washington Post* newspaper on January 28, 1999. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this ad and has determined that it promotes Coreg (carvedilol) tablets in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, it is false or misleading, and lacking in fair balance.

Promotional materials are false or misleading, and lacking in fair balance if they fail to present information relating to the risks associated with the use of the drug with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the drug. Many claims in this ad, relating to the benefits of Coreg therapy, are written in terminology that can be understood by members of the general public, especially those who have heart failure. For example, in the banner at the top of the ad, SB states that "heart failure is a condition that occurs when the heart weakens and loses some of its pumping ability." SB follows this statement with the following claims for Coreg:

- Panel of 156 Heart Failure Experts Endorses the Use of Beta Blockade in Heart Failure
- ...beta blockers can decrease the...combined risk of death or hospitalization.
- Carvedilol [Coreg] is the only agent with beta blockade approved by the FDA for the management of chronic heart failure.

Presentation of these efficacy claims for beta blocker therapy, in conjunction with the statement that Coreg is the only beta blocker approved for the management of heart failure, clearly

provides even non-healthcare professionals with an understanding of the benefits of Coreg therapy.

However, information pertaining to the risks of Coreg therapy is not similarly comprehensible when compared to the efficacy claims. For example, SB presents that "*Coreg* is contraindicated in NYHA Class IV *decompensated* heart failure requiring intravenous inotropic therapy, bronchial asthma, or related bronchospastic conditions, second- or third-degree AV block, sick sinus syndrome (unless a permanent pacemaker is in place), cardiogenic shock, or severe bradycardia."

Therefore, in this ad, SB presents claims for the benefits of Coreg therapy in a manner that encourages readability by a wide audience, including those who are not healthcare providers, while risk information is presented in a manner that may only be comprehensible to healthcare providers. Thus, DDMAC considers this ad to be misleading and lacking in fair balance because information relating to the risks associated with the use of Coreg are not presented with a readability reasonably comparable to the presentation of information relating to the effectiveness of Coreg.

SB should immediately cease distribution of this and other similar promotional materials for Coreg that contain the same or similar claims or presentations. SB should submit a written response to DDMAC on or before February 23, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, SB should include the date on which this and other similarly violative materials were discontinued.

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 matter, please refer to MACMIS ID #7559 in addition to the NDA number.

Sincerely,

/S/

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