DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTED VIA FACSIMILE

DEC 21 1998

Richard Swenson, Ph.D.
Associate Director, U.S. Regulatory Affairs
SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

RE: NDA 20-671/S-004
Hycamtin (topotecan HCl)
MACMIS #7419

Dear Dr. Swenson:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Hycamtin (topotecan HCl) by SmithKline Beecham (SB) that violate the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Reference is made to a **Convention Panel (HY982P-PA)**, submitted under cover of Form FDA 2253 on December 7, 1998. DDMAC has reviewed this material and has determined that it contains promotional claims that are false or misleading and lacking in fair balance. DDMAC requests that the use of the above referenced material and those containing similar promotional claims cease immediately.

THEME/TAGLINE

SB's use of the unqualified tagline, "Hycamtin: Combining clinical efficacy with symptom improvement" is misleading because it suggests an effect of the drug that has not been demonstrated by substantial evidence. Notwithstanding the approved labeling, which lists the percentages of patients who had some effect on certain symptoms, SB's use of this broad tagline without adequate context is unsubstantiated.

RISK INFORMATION

Promotional materials are lacking in fair balance, or otherwise misleading if they fail to present information relating to the contraindications, warnings, precautions, and side effects associated with the use of the drug in a manner reasonably comparable to the presentation of efficacy information. The approved product labeling for Hycamtin includes a boxed warning and lists several precautions and adverse reactions associated with the use of the drug. However, SB fails to include any risk information in the convention panel..

SB should immediately cease using the convention panel, and all other promotional materials for Hycamtin that contain the same or similar claims or presentations. SB should submit a written response to DDMAC, on or before January 6, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, SB should include a list of all promotional materials that were discontinued, and the discontinuation date.

SB should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds SB that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS #7419 and NDA 20-671/S-004.

Sincerely,

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications