DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDT

Food and Drug Administration
Rockville MD 20857

MAR 20 1997

TRANSMITTED VIA FACSIMILE

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

RE: **NDA#** 20-671
Hycamtin (topotecan HCl)
MACMIS ID # 5242

Dear Dr. Swenson:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware that SmithKline Beecham (SB) is promoting its product in a manner that is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. Specifically, we refer to press releases issued in November, 1996.

UNSUBSTANTIATED SUPERIORITY CLAIMS

SB makes claims in its press releases that patients treated with topotecan experienced a higher response rate and a longer duration of response compared to patients treated with paclitaxel. The comparison of response rates and duration of response between topotecan and paclitaxel in the clinical trial reported in this press release failed to achieve statistical significance. Therefore, claims of superiority of topotecan over paclitaxel with respect to response rate or response duration are misleading. SB was informed that DDMAC held this position in our letter to SB dated, May 29, 1996.

FAILURE TO COMPLY WITH 21 CFR § 314.81(b)(3)(i)

Press releases are considered to be promotional labeling. As such, a sponsor is required to submit them to FDA at the time of initial dissemination. SB has not submitted the above referenced press releases to FDA in accordance with this regulation.

In order to address the above violations, DDMAC recommends SB take the following actions:

1. Immediately discontinue all promotional materials that contain the types of claims and representations discussed in this letter, and all similarly violative claims.

2. Provide a list of all materials responsive to #1.

3. Provide to DDMAC in writing SB's intent to comply with items 1 and 2 above. Please address your response, to be received by April 3, 1997, to the undersigned 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 SB that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID # 5242 in addition to the NDA number.

Sincerely,

Tracy L. Acker, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

File Name:topotecan/NOV.314

Drafted: Acker March 14, 1997
Concur: Abrams March 18, 1997

CC:
HFD-40/NDA # 20-671
HFD-40/Chron/Acker/Abrams
HFD-150/NDA #20-671
HFD-150/Hirschfeld/Catterson

MACMIS ID #5242

MACMIS Type Code:LETT
MACMIS Action Code:viol

Close Out: no

Due Date:April 3, 1997

FOI STATUS: RELEASABLE