DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE SEP 1 0 1999

Bradley Carver
President
SafeScience, Inc.
31 St. James Avenue, Suite 520
Boston, MA 02116

dd

Re: GBC-590
IND[ ]
MACMIS ID# 8246

Dear Mr. Carver:

It has come to the attention of the Division of Drug Marketing, Advertising, and Communications (DDMAC) that SafeScience (SS) is promoting GBC-590 prior to approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations (see 21 CFR 312.7).

On July 26, 1999, SS issued a press release regarding early clinical trials of GBC-590. This press release is posted on SS's website. The press release makes numerous claims regarding the safety and efficacy of GBC-590. These claims are based solely upon preliminary and inconclusive data since the clinical investigation of GBC-590 is in a preliminary stage; neither the safety nor efficacy of the drug has been demonstrated by substantial evidence (i.e., adequate and well-controlled studies). Therefore, the press release is in violation of the Act and its implementing regulations because it promotes an investigational new drug.

Following are selected statements from the press release that promote the drug as safe and/or effective:

> *The results show that the compound is well-tolerated at all administered dose levels. These data confirm the excellent safety profile which was first reported in the GBC-590 Phase I trial in prostate cancer....*
>
> *GBC-590 has consistently demonstrated, across many aggressive tumor types, a good safety* profile.... *In both Phase 1 trials we noted both quantitative and qualitative improvement in a number of patients.... Further, the quality of life of several end-stage cancer patients appeared to improve while being treated with GBC-590.*

We believe that GBC-590 holds promise in offering hope to cancer patients that have failed all other therapies....

GBC-590's affinity for cancer cell lectins is the core reason for its significant biological activity and specificity that has been demonstrated in clinical and preclinical trials with multiple forms of cancer. With the current formulation of GBC-590, an excellent safety profile has been observed in clinical and preclinical trials, and GBC-590 has shown it can shrink tumors as well as arrest tumor growth in several preclinical studies.

Since a New Drug Application (NDA) for GBC-590 has not been approved for marketing by the Food and Drug Administration (FDA), the dissemination of materials by SS that represent in a promotional context that GBC-590 is safe and effective constitutes promotion of an investigational drug, in violation of the Act.

DDMAC requests that the distribution and use of materials that promote GBC-590 prior to approval cease immediately, including but not limited to, removal of violative press releases from the SS website. SS should submit in writing, on or before September 24, 1999, a description of the steps that will be taken to comply with the above request.

SS 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 20847. DDMAC reminds SS that only written communications are considered official. In all future correspondence regarding this matter, please refer to MACMIS ID# 8246 and IND[ ]

Sincerely,

/S/

Jean-Ah Choi, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications