DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

APR 28 1999

**TRANSMITTED VIA FACSIMILE**

Clare Kahn, Ph.D.
Group Director
U.S. Regulatory Affairs
SmithKline Beecham Pharmaceuticals
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

**RE:**
Avandia (rosiglitazone maleate) Tablets
MACMIS ID #7902

Dear Dr. Kahn:

As part of its routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a promotional labeling piece for Avandia (rosiglitazone maleate) tablets, disseminated by SmithKline Beecham Pharmaceuticals (SB), that is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations. DDMAC specifically refers to SB's April 23, 1999, press release entitled "FDA Advisory Committee Unanimously Recommends SmithKline Beecham's Avandia for Treatment of Type 2 Diabetes." This press release is considered promotional labeling for Avandia and is in violation of the Act for the following reasons.

Pre-Approval Promotion

Section 21 CFR 312.7 states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. SB's April 23, 1999, press release is considered to be violative because it promotes the safety and efficacy of Avandia, an investigational new drug. These claims include statements about the Avandia's intended use in the treatment of type 2 diabetes and other conclusions about the safety and efficacy of the drug such as:

"Avandia represents a significant advance in the treatment of diabetes and is highly effective in safely and significantly lowering blood sugar."

"[Avandia] has dramatically improved my patients' conditions, making them feel better and motivating them to take an active role in managing their disease."

"...because of its high potency, only a small dose of Avandia is needed to achieve therapeutic control...."

"Avandia can help the millions of people with type 2 diabetes lower their blood sugar levels and help prevent life-threatening complications."

In order to address these objections, DDMAC recommends that SB take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for Avandia that contain the same or similar violations.

2. Provide to DDMAC, in writing, SB's intent to comply with #1 above. Your response should be received by May 12, 1999.

3. This response should include a list of all similarly violative promotional materials and SB's method for discontinuing their use.

If SB has any questions or comments, please contact 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 you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #7902 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications