DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUN 29 19

TRANSMITTED VIA FACSIMILE

Sharon Shapowal, R.Ph.
Associate Director
U.S. Regulatory Affairs
SmithKline Beecham Pharmaceuticals
P.O. Box 5089/M.C. UP 4340
Collegeville, PA 19426-0989

RE: NDA 21-071
Avandia (rosiglitazone maleate) Tablets
MACMIS ID #8072

Dear Ms. Shapowal:

As part of its routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of several promotional labeling pieces for Avandia (rosiglitazone maleate) tablets, disseminated by SmithKline Beecham Pharmaceuticals (SB), that are in violation of the Federal Food, Drug and Cosmetic Act (Act) and its implementing regulations. Specifically, the following promotional labeling pieces for Avandia, submitted under cover of Form FDA 2253, are in violation of the Act because they lack fair balance.

- Dear Buyer Letter (AV0516)
- Dear Pharmacist Letter (AV1115)
- Dear Wholesaler Letter (AV0523)
- Dear Manager Letter (AV0521)
- Sell Sheet (AV0517)
- Dear MCO, Director, or Hospital Letter (AV1117)
- Letter to Federal Accounts (AV1278)
- Letter to State Accounts (AV1119)

Promotional materials are misleading if they fail to present a fair balance between information relating to the risks associated with the use of the drug and information relating to the effectiveness of the drug. SB's materials for Avandia, listed above, include claims or representations about the use of Avandia including, but not limited to, "Avandia addresses insulin resistance," "...a new insulin sensitizer," and "an important new treatment for the management of Type 2 diabetes" without presenting any information concerning the risks associated with the drug.

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

1. Immediately discontinue the use of these, 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 July 14, 1999.

3. This response should include the date that these materials were discontinued, 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 #8072 in addition to the NDA number.

Sincerely,

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