DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC - 3 1997

TRANSMITTED VIA FACSIMILE

Eloise R. Scott, D.V.M.
Associate Director, U.S. Regulatory Affairs
Smithkline Beecham Pharmaceuticals
1250 Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

RE: **NDA #20-658**
Requip (ropinirole HCl) Tablets
MACMIS #5868

Dear Dr. Scott:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of certain claims and promotional activities by Smithkline Beecham Pharmaceuticals (SKB) for Requip (ropinirole HCl) Tablets that are false, misleading, and in violation of the Federal Food, Drug, and Cosmetic Act. DDMAC refers to a September 22, 1997, press release on PR Newswire entitled "New Parkinson's Disease Drug Requip (TM) from SmithKline Beecham Cleared for Use by FDA."

Specifically, DDMAC objects to the claim that effectively treating early stages of Parkinson's disease with Requip, over a long period of time, may improve the "quality of life for patients and their families." This claim, a quotation by Emilio Alonso-Mendoza, is misleading because it is not supported by substantial evidence. There have been no adequate and well-controlled studies examining the potential of Requip to improve quality of life for patients or their families.

To address this objection, DDMAC recommends that SKB immediately discontinue the use of this press release and all other promotional materials for Requip that contain the same or similar presentations. Please respond to this letter, in writing, by December 12, 1997. This response should include a list of all violative promotional materials that include the same or similar issues, and SKB's methods for discontinuing their use.

If SKB 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.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5868 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications