DEPARTMENT HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 24 1997

TRANSMITTED VIA FACSIMILE

Isabel Drzeweicki
Senior Director, Regulatory Affairs
R. W. Johnson Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan, NJ 08869-0602

RE: NDA# 19-697, 20-681
Ortho Tri-Cyclen (norgestimate and ethinyl estradiol) Tablets
MACMIS # 5807

Dear Ms. Drzeweicki:

Reference is made to R. W. Johnson Pharmaceutical Research Institute's (RWJPRI) direct-to-consumer (DTC) advertisement "Announcing a birth control pill that's also a beauty aid" (enclosed) that has recently appeared in college publications throughout the country. The Division of Drug Marketing, Advertising and Communications (DDMAC) has determined that this DTC advertisement is misleading and lacking in fair balance, and thus in violation of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, this advertisement is misleading because it implies that the product will promote "beauty." Clinical studies have demonstrated that Ortho Tri-Cyclen is effective in improving moderate acne in women over the age of fifteen who desire contraception and who are unresponsive to topical anti-acne medication. Further, the approved product labeling (PI) states that Ortho Tri-Cyclen decreased the severity of facial acne with a mean percent reduction in total lesions of about 20% over placebo. The claim that Ortho Tri-Cyclen is a "beauty aid" implies a much broader range of improvement than has been demonstrated.

RWJPRI should immediately discontinue the use of this and all other promotional materials for Ortho Tri-Cyclen that contain the same or similar presentations. Please respond to these comments in writing by October 3, 1997. This response should include a list of all violative materials that have been discontinued and RWJPRI's methods for discontinuing their use.

If you have 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 # 5807 in addition to the NDA number.

Sincerely,

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