DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY - 5 1999

TRANSMITTED VIA FACSIMILE

James A. Parker, Jr.
Director, Advertising and Labeling
Worldwide Drug Regulatory Affairs
Parke-Davis
201 Tabor Road
Morris Plains, NJ 07950

RE: NDA# 20-130
Estrostep (norethindrone acetate and ethinyl estradiol) Tablets
MACMIS # 7909

Dear Mr. Parker:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed a journal ad for Estrostep (norethindrone acetate and ethinyl estradiol) Tablets that is lacking fair balance, and thus is in violation of the Federal Food, Drug and Cosmetic Act.

Specifically, the journal ad #PD-028-JA-3254-A1(019) is lacking fair balance because the risk information is presented in micro-sized font at the bottom of the page. Similarly, the directive to seek other important information about Estrostep is presented in tiny type font. Thus, this promotional piece is lacking in fair balance because the risk information is not presented with a prominence and readability that is reasonably comparable to the presentation of information relating to the effectiveness of the drug.

To address this issue, DDMAC requests that this journal ad be immediately discontinued along with any other materials with the same or similar violations. Parke-Davis should respond, in writing, to this request within 10 business days of the date of this letter. Your response should include your intent to comply with DDMAC's request and the materials that will be discontinued as a result of this letter.

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 #7909 in addition to the NDA number.

Sincerely,

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