DEPARTMENT OF HEALTH & HUMAN SERVICES

FOI

Food and Drug Administration
Rockville MD 20857

JAN 2 6 1999

TRANSMITTED VIA FACSIMILE

Ron Lapré
Senior Director, Regulatory Affairs
Watson Laboratories, Inc.
311 Bonnie Circle
P.O. Box 1900
Corona, CA 91718-1900

RE: NDAs 74-538, 72-721, 70-687, 73-594, 17-060
Trivora (levonorgestrel and ethinyl estradiol, USP) Tablets
Zovia (ethnodiol diacetate and ethinyl estradiol, USP) Tablets
Necon (norethindrone and ethinyl estradiol) Tablets
Levora (levonorgestrel and ethinyl estradiol) Tablets
Nor-QD (norethindrone) Tablets
MACMIS # 7514

Dear Mr. Lapré:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a sales aid (ID# # W-12018) for Trivora, Zovia, Necon, Levora, and Nor-QD Tablets, that is considered to be false, misleading, or otherwise in violation of the Federal Food, Drug and Cosmetic Act. This sales aid was disseminated on November 11, 1998, and was submitted to the Agency on Form FDA 2253, as required by the regulations.

DDMAC also refers to the untitled letter dated August 6, 1998 that addresses this promotional piece. As stated in the August 6, 1998 letter, DDMAC objects to claims that imply that one oral contraceptive is unique or superior to another because of its progestin. There are no adequate and well-controlled studies that demonstrate that Trivora can "minimize androgenic side effects such as hirsutism, chronic anovulation, polycystic ovarian disease, acne, bloating and weight gain, reduced libido." Thus, this is a misleading presentation. Also, the statement that triphasic regimens "mirror the natural female cycle" is misleading because it implies, without adequate substantiation, that triphasic oral contraceptives are superior to other oral contraceptives because they have a quality that is more physiological.

Furthermore, the sticker that has been added to this visual aid to correct a fair balance issue that was discussed in the August 6, 1998, untitled letter is inadequate to correct the balance. The corrective sticker appears in tiny font at the bottom corner of the seventh page of this eight-page document, while the violative balance statement remains on the page presenting claims of efficacy. Thus, the appropriate risk information does not have prominence and readability comparable to the presentation of information relating to the effectiveness of Trivora.

DDMAC is very concerned about these claims continuing to appear in Watson's promotional materials.

DDMAC requests that Watson immediately discontinue this and any other promotional materials, or activities, that involve the same or similar messages. Watson should respond, in writing, with its intent to comply with DDMAC's request by February 2, 1999. This response should include a list of all violative materials that have been discontinued and a description of Watson's plan for addressing the issue.

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 # 7514 in addition to the NDA number.

Sincerely,

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