DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC - 1 1998

TRANSMITTED VIA FACSIMILE

Tom Der
Manager, Regulatory Affairs
Monarch Pharmaceuticals
355 Beecham Street
Bristol, TN 37620

RE: ANDA #84-951, 84-948, 84-950, 84-949
Menest (esterified estrogen tablets, USP)
MACMIS #7336

Dear Mr. Der:

Reference is made to Monarch Pharmaceuticals' (Monarch) October 13, 1998, letter to the Division of Drug Marketing, Advertising and Communications (DDMAC) requesting comments on a proposed promotional materials for Menest (esterified estrogen tablets, USP), and to DDMAC's comments dated November 10, 1998.

We also refer to Monarch's letter dated November 25, 1998. In that letter, Monarch states that, prior to receipt of DDMAC's comments, one journal advertisement for Menest was sent to four medical journals for publication. Upon receipt of DDMAC's comments, Monarch noted that, in FDA's view, the journal advertisement was false or misleading and lacking in fair balance.

Specifically, the journal advertisement is in violation of the Federal Food, Drug and Cosmetic Act because:

1. The claim that Menest is "the natural choice" is misleading because the claim falsely implies that Menest is the only soybean-derived, or otherwise "naturally" derived, estrogen. Also, the claim is misleading because it implies that Menest is superior because it is "natural."

2. The journal ad in fair balance because the risk information is in very tiny print at the bottom of the ad. Thus, it is not presented with a prominence and readability that is reasonably comparable with the presentation of the information relating to effectiveness.

Furthermore, DDMAC notes that Monarch has failed to properly submit this journal advertisement to the Agency in accordance with 21 CFR §314.81 that requires that

sponsors submit specimens of all promotional materials at the time of initial dissemination, and that each submission must be accompanied by FORM FDA 2253.

In Monarch's November 25, 1998, letter, Monarch states that it has revised promotional materials with the same or similar presentations. Also, Monarch states that it has discontinued future distribution of this particular journal advertisement. DDMAC thanks Monarch for its vigilance and considers this matter to be closed.

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 #7336 in addition to the NDA number.

Sincerely,

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