DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 16 2003

Nicholas Tantillo
Senior Director, Regulatory Affairs
Barr Laboratories, Inc.
2 Quaker Road
P. O. Box 2900
Pomona, NY 10970-0519

Re: Docket No. 02P-0399/CP1

Dear Mr. Tantillo:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated September 4, 2002. Your petition requests that FDA determine whether Estrostep 21 (ethinyl estradiol and norethindrone acetate; 0.02 mg/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 mg) Tablets have been withdrawn or withheld from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your request because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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