DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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DEC 4 2001

Gail Elbek
380 N. San Marcos Road
Santa Barbara, CA 93111

Re: Docket No. 01P-0443/CP1

Dear Ms. Elbek:

This letter responds to your citizen petition dated September 25, 2001, filed on behalf of your organization, People Erroneously On Prescribed Lethal Estrogen (PEOPLE). You request that the Food and Drug Administration (FDA) review and revise public and physician information on estrogen and progestin drug products to include factual risk and benefit information. You state that labeling information on these drug products is not consistent with factual documentation, which you state is a violation of the laws under which drugs are marketed and prescribed.

While you cite provisions of the Federal Food, Drug, and Cosmetic Act and FDA's regulations that you believe are being violated, you do not support these allegations with factual information. While you allege labeling violations, you do not provide us with any specific labeling information you believe to be false. You also allude to information on fatal side effects that you believe is being withheld from public view, but you do not provide us any information to support your statement. While we appreciate your obvious concern on these issues, without factual support for your allegations it is difficult for us to pursue them.

Let me assure you that FDA is continually reviewing the labeling on approved drug products containing estrogen and progestin based on new scientific data. We are aware that millions of women use these drug products on a daily basis for treatment of menopausal symptoms or to prevent osteoporosis. When we determine that labeling changes are necessary, our division of Reproductive and Urologic Drug Products works with drug manufacturers to require new labeling statements as soon as possible.

Our current efforts related to conjugated estrogens are posted on our website at http://www.fda.gov/cder/regulatory/initiatives/cestrogens. On our website you will find background information on conjugated estrogens, as well as new scientific methods we have proposed for characterizing these drug products, and new monograph requirements we are proposing to the United States Pharmacopeia.

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Again, let me stress that FDA works to ensure that currently marketed estrogen and progestin drug products are safe and effective, and that the labeling for such drug products is current and accurate. However, because your petition provides no specific scientific, medical, or persuasive legal support for your request, your petition is denied.

Sincerely yours,

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