DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 12 2007

Cynthia Pearson
Executive Director
National Women's Health Network
514 Tenth Street, N.W.
Suite 400
Washington, D.C. 20004

Re: Docket No. 2006P-0346/CP1

Dear Ms. Pearson,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received by the Agency on August 22, 2006. Your petition requests that we stop Solvay Pharmaceuticals and Breckenridge Pharmaceuticals from marketing esterified estrogens and methyltestosterone combination products for vasomotor symptoms associated with menopause that do not respond to treatment with exogenous estrogen alone.

We have been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0346

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