



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA 305

Food and Drug Administration
Rockville MD 20857

AUG 12 2002

Neal D. Barnard, M.D.
President
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave., NW
Suite 400
Washington, DC 20016

Docket No. 02P-0067/CP1

Dear Dr. Barnard:

This letter responds to your citizen petition dated February 5, 2002, requesting that the Food and Drug Administration (FDA) include new advisories in the product labeling for products containing estrogens intended for oral use.

FDA has been unable to reach a decision on your petition due to 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 possible, given the numerous demands on the Agency's resources.

Sincerely yours,

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

02P-0067

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