



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 30 2004

Ekkehard Kemmann, M.D.
Robert Wood Johnson University Medical Group
University of Medicine and Dentistry of New Jersey
303 George Street, Suite 250
New Brunswick, NJ 08901

Re: Docket No. 2004P-0122/CP1

Dear Dr. Kemmann:

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 March 3, 2004. Your petition requests that the labeling for estradiol-containing drug products not designate these products as pregnancy category X.

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,

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

2004P-0122

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