



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAR 31 2006

1800 6 APR -5 19:43

Andrew S. Krulwich  
Benjamin B. Reed  
Sarah E. Botha  
Wiley Rein & Fielding LLP  
1776 K Street, N.W.  
Washington, D.C. 20006

Re: Docket No. 2005P-0411/CP1

Dear Messrs. Krulwich and Reed and Ms. Botha:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition submitted on October 6, 2005, on behalf of Wyeth. Your petition requests that the Agency take various actions with respect to bio-identical hormone replacement therapy drugs that are available from compounding pharmacies.

FDA has 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  
Associate Director for Policy  
Center for Drug Evaluation and Research

2005P-0411

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