



**National Partnership**  
*for Women & Families*

November 23, 2005

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

**RE: Docket Number 2005P-0411**

Dear Sir or Madam:

The National Partnership for Women & Families is a nonprofit, nonpartisan organization that uses public education and advocacy to promote fairness in the workplace, quality health care, and policies that help women and men meet the dual demands of work and family. The National Partnership is committed to ensuring that women and their families have access to safe, affordable, quality health care. To advance these goals, we have forged a unique collaboration of leading employers and consumer and health groups to leverage our shared interest and common goal of making the U.S. health care system safer and more accountable.

Consistent with our goal of improving the quality of care, we are committed to helping build a health care system that provides consumers with the information they need to make better health care decisions. Unfortunately, consumers are often bombarded with false and misleading health information that is confusing and potentially dangerous. The National Partnership believes that the area of bio-identical hormone replacement therapy is an example of a deceptive marketing campaign that potentially threatens women's health. We urge the Food and Drug Administration (FDA) to take appropriate enforcement action against some compounding pharmacies that are making false and misleading promotional claims for bio-identical hormone replacement therapy (BHRT) drugs in violation of the Federal Food, Drug, and Cosmetic Act (FDCA).

In order for consumers to be better equipped to make informed health care decisions, they need accurate, evidence-based health information. Much of the BHRT promotional materials that the National Partnership has reviewed, however, are completely devoid of scientific substantiation. Unsupported comparative claims of superiority are unfortunately convincing many women that BHRT products are interchangeable with FDA-approved hormone therapies, despite the fact that these products have not undergone the rigorous safety and effectiveness testing normally required for approval of new drugs.

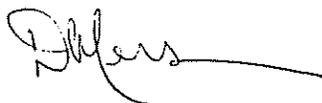
These misleading and unsubstantiated safety claims are also in direct conflict with the FDA-developed science-based *Menopause & Hormones* informational campaign materials. At the September 2003 press conference announcing the campaign, Commissioner McClellan stood with Members of Congress and women's health and medical professional groups and stressed that "it is very important that women realize that this beneficial therapy [i.e., postmenopausal hormone therapy] also carries significant risks" (FDA press release, September 9, 2003). Communication of this risk information for BHRT products seems to be frequently lacking, however.

The National Partnership understands that the FDA has exempted legitimate compounding of drugs from the testing requirements of the FDCA. However, the key word here is "legitimate." We believe that the practice of mass-producing BHRT and conducting extensive misleading marketing campaigns in support of these products does not constitute legitimate compounding, and hence should trigger FDA regulation.

The National Partnership urges the Food and Drug Administration to take action to address this problem before it becomes even more widespread.

Thank you for your consideration of our views on this important women's health issue.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Ness", with a long horizontal flourish extending to the right.

Debra L. Ness  
President

cc: Sheldon T. Bradshaw, Chief Counsel, Office of the Chief Counsel  
Dr. Kathleen Uhl, Director, Office of Women's Health  
Dr. Janet Woodcock, Deputy Commissioner for Operations