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A S S O C I A T I O N O F R E P R O D U C T I V E H E A L T H P R O F E S S I O N A L S

November 28, 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:

I am writing on behalf of the 11,000 core members and professional associates of the Association of Reproductive Health Professionals (ARHP) to express our concern about the current promotion of compounded bio-identical hormone replacement therapy (BHRT) products. The safety and efficacy of these products are currently unknown and, unlike FDA-approved hormone therapies, no safety or effectiveness studies have been conducted.

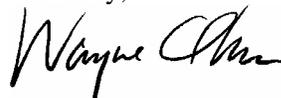
ARHP is a non-profit membership association comprised of highly qualified and committed experts in reproductive health. Our members are professionals who provide reproductive health services and education, conduct reproductive health research, and influence reproductive health policy, and they include physicians, nurse practitioners, nurse midwives, physician assistants, researchers, educators, pharmacists, and other professionals in reproductive health.

As an original member of the FDA's working group on hormone therapy, ARHP is deeply committed to sound, evidence-based research to support hormone therapy treatment options. Hormone therapy decisions must be individualized for each woman, and reproductive health professionals stand ready to help patients make appropriate treatment decisions.

As a service to our members and the public at large, ARHP established an online *Menopause Resource Center*. The *Resource Center* guides health care providers, the media, and the general public through the vast array of resources on menopause available on the web, including information and links to the latest information about hormone therapy. Along with many of our colleagues in the health professional and women's health advocacy communities, ARHP believes that it would be very helpful for FDA to produce an Alert or Talking Paper to inform patients, health care providers, and pharmacies that FDA has neither approved compounded BHRT products as safe and effective, nor determined that they are safer or more effective than FDA-approved HT products.

While ARHP strives to educate health professionals and patients about the appropriate use of hormone therapy, the FDA's leadership on this issue is clearly needed. We urge FDA to take prompt action on this important women's health issue.

Sincerely,



Wayne C. Shields
President and CEO

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