

December 21, 2005

Division of Dockets Management
FDA
5630 Fishers Lane Room 1061 (HCFA-305)
Rockville MD 20852

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Dear Sirs and/or Madams:

My name is Jim Richards and I've been practicing pharmacy for 28 years. Furthermore I practice in a compounding pharmacy setting where I dispense bio-identical hormones for my patients. BHRT (bio-identical hormone replacement therapy) has been a tremendous comfort and logical choice over synthetic hormones for greater than 95% of my patients who are using this form of hormone therapy. I consult with my patients and with their physicians to design and prepare BHRT specifically for that patient based on symptomology and salivary testing of hormones. This is a greater advantage over synthetic hormones for many reasons but primarily it is individualized treatment and not a "stab in the dark" as is the case with synthetic hormones. Synthetic hormones are not the same as hormones that are naturally produced in the body so it makes more sense medically to treat symptoms of hormone imbalance with biologically identical medications.

Then benefit of BHRT is that it is designed individually for each patient and I am concerned that Wyeth's petition (Docket 2005p-0411) would limit my ability to keep dispensing these individualized doses for my patients. As a result, the FDA should reject Wyeth's petition.

Sincerely,



Dr. Jim Richards, Registered Pharmacist
Corner Drugs, Chatsworth GA

2005P-0411

CORNER DRUGS, INC
430 N. 3RD AVE
CHATSWORTH GA 30705

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