



NATIONAL CONSUMERS LEAGUE

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BY ELECTRONIC MAIL

<http://www.fda.gov/dockets/ecomments>

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 Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation's oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL has long been involved in issues of healthcare and monitors rulemakings and legislation involving health, provides and participates in patient education on medication and disease awareness, and researches factors that influence the provision of medical services to patients. NCL has worked extensively on issues surrounding communication of information to consumers about the drugs they take, and is committed to building a health care system that provides consumers with the appropriate, useful, and accurate information they need to make critical decisions about their health.

Unfortunately, consumers too often have insufficient information available to make these decisions and, even worse, often are presented with false or misleading information that can confuse and even cause serious harm. The

issue of bio-identical hormone replacement therapy (BHRT) appears to be an example of both, as it attempts to confuse women about the presence (or absence) of active hormone therapy, and claims erroneously that this absence will safeguard women from the potential harmful effects of “traditional” HRT. For these reasons, NCL supports the Citizen Petition entitled “Citizen Petition Seeking FDA Actions to Counter Flagrant Violations of the Law by Pharmacies Compounding Bio-Identical Hormone Replacement Therapy Drugs that Endanger Public Health.”

The National Consumers League recognizes that many women are confused about how to treat their menopausal symptoms. To help menopausal women make informed decisions about hormone therapy, NCL launched an educational effort entitled *MenoPAUSE: Take Time to Talk about Your Symptoms*. This campaign was designed to help women assess their menopausal symptoms and facilitate a productive discussion with their healthcare professional. In addition to our educational campaign, NCL also participated in the development of key messages for FDA’s *Menopause and Hormones Information Campaign*. These educational efforts have gone a long way towards eliminating much of the confusion surrounding the appropriate role of hormone therapy. However, the misleading advertising of BHRT threatens to further confuse consumers and entice them into buying questionable therapies.

In order for consumers to make informed healthcare decisions and take their medications appropriately, it is critical that they receive adequate instructions for use at the point of sale, as well as truthful and accurate information on both drug benefits and risks. NCL is alarmed, therefore, that some compounding pharmacies apparently do not distribute the required patient package insert with BHRT products. NCL urges FDA to make certain that compounding pharmacies include BHRT package inserts that are in compliance with the agency’s regulations and guidance documents.

NCL also is concerned about both unsubstantiated claims that some BHRT products are safer or more effective than FDA-approved HRT products, and the apparent mass production of many BHRT products. NCL recognizes that the FDA has exempted legitimate compounding of drugs for important reasons, but takes issue with the current practice of many compounding pharmacies that essentially mass-produce BHRT – thereby avoiding the testing requirements of the Food, Drug, and Cosmetics Act.

NCL is deeply troubled by the current situation, and urges the FDA to initiate an investigation into the above-mentioned practices of numerous compounding pharmacies, which are – at best – misleading and at worst unlawful. Furthermore, should FDA determine that violations of the Federal Food, Drug, and Cosmetic Act have taken place, then the Agency must take appropriate enforcement actions in order to stem such illegal activities.

Thank you for your consideration of this important issue.

Sincerely,

LINDA F. GOLODNER
President,
National Consumers League