



U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, D.C. 20416

OFFICE OF THE NATIONAL OMBUDSMAN

March 4, 2008

Thank you for your correspondence concerning a U.S. Food and Drug Administration's (FDA) policy regarding compounded bio-identical hormone replacement therapy (BHRT).

I referred your concerns to the U.S. Food and Drug Administration for a high-level review and a response. I am pleased to enclose a copy of FDA's response with this letter.

The Office of the National Ombudsman was created by Congress under the Small Business Regulatory Enforcement Fairness Act (SBREFA) to receive comments from small businesses regarding concerns of unfair or excessive Federal regulatory actions.

Should you have any questions or concerns in this matter, please contact my office by telephone at (202) 205-2417, fax at (202) 481-5719 or e-mail at Ombudsman@sba.gov.

Thank you for bringing your concerns to my attention.

Sincerely yours,

Nicholas N. Owens
National Ombudsman and
Assistant Administrator for Regulatory Enforcement Fairness

Enclosures

The Mission of the Office of the National Ombudsman:
FOSTERING A MORE BUSINESS FRIENDLY REGULATORY ENFORCEMENT ENVIRONMENT.

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Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

February 14, 2008

Mr. Nicholas N. Owens
National Ombudsman and Assistant Administrator
for Regulatory Enforcement Fairness
U.S. Small Business Administration
409 3rd Street, S.W, MC 2120
Washington, D.C. 20416-0005

Dear Mr. Owens:

Thank you for your letters to me dated January 17, 2008, and January 28, 2008, concerning the Food and Drug Administration's (FDA) policy regarding compounded bio-identical hormone replacement therapy (BHRT).

The FDA recently sent letters warning seven pharmacy compounding operations that the claims they make about the safety and effectiveness of their BHRT products are unsupported by medical evidence and are considered false and misleading by the agency. Specifically, the pharmacy operations that received these warning letters have made unsupported claims that their drugs can be used to prevent and treat serious diseases such as Alzheimer's disease, stroke, or various forms of cancer, and many of these operations have also made unsupported claims that their drugs are better than FDA-approved menopausal therapy drugs. These pharmacy operations violated federal law by making these false and misleading claims about their products, and FDA is concerned that the unfounded claims for these products mislead women and health care professionals.

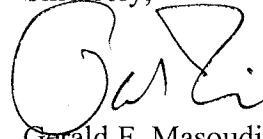
These pharmacy operations also compound BHRT products that contain the drug ingredient estriol; the safety and effectiveness of estriol is unknown, and FDA has never approved a drug product containing estriol. It is not the case, however, the FDA's action has made estriol unavailable for treatment. Physicians wishing to treat their patients with drugs containing estriol may submit an investigational new drug application, the process for which is described at http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm.

It is important to note that FDA's action does not target pharmacists who practice traditional pharmacy compounding and who do not make false or misleading claims about their compounded products. Traditional pharmacy compounding typically involves preparation of a drug for an individual patient by a pharmacist in response to a valid prescription from a licensed practitioner. This compounding generally follows a practitioner's decision that his or her patient has a special medical need that cannot be met by FDA-approved drugs.

More information about the agency's recent action with respect to the seven pharmacy compounding operations, as well as FDA's current view on human drug compounding, is available at <http://www.fda.gov/cder/pharmcomp/default.htm>.

Please let me know if you have any further questions about this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. Masoudi', written in a cursive style.

Gerald F. Masoudi
Chief Counsel
Food and Drug Administration