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From: kmills@amwa-doc.org
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Subject: comments from AMWA



FeldmanTestimony.doc

Attached are comments for the June 8 FDA meeting. please call me at 703-838-0500 if you have any questions.

Thank you,
Kelli Mills
American Medical Women's Association

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**COMMENTS OF THE AMERICAN MEDICAL WOMEN'S ASSOCIATION
PRESENTED BY: ELAINE B. FELDMAN, M.D.**

Professor Emeritus of Medicine and Physiology & Endocrinology, the Medical College of Georgia, Chief Emeritus, Section of Nutrition

Thank you for the opportunity for the American Medical Women's Association (AMWA) to submit written comments. AMWA is a national organization of 10,000 women physicians and medical students dedicated to promoting women's health and the advancement of women physicians. The issue of dietary supplements is important to women's health, and I am grateful to be able to submit written comments on behalf of AMWA.

The current regulation of dietary supplements should be changed for many reasons and should become more rigorous. Under the DSHEA act of 1994 the role of the FDA was weakened, the dietary supplement appellation was redefined to include non-nutritional compounds, and regulations regarding health claims and promotion altered. This has resulted in the current situation in which a dietary supplement is less regulated by the FDA than a food, and much less than over-the-counter drug products.

A dietary supplement, although not a food product, should have nutritional usefulness and value. This definition applied prior to the 1994 legislation. Since then, herbals and botanical, and various chemicals which in reality are taken for medicinal purposes (health promotion, disease prevention, and disease treatment) are now included in a relatively unregulated setting. The FDA has lost the previous authority of pre-clearance of these substances for efficacy and safety, but rather has an after-the-fact policing function. Although a food additive is required to be generally regarded as safe (GRAS), this requirement no longer applies to dietary supplements. AMWA recommends a return to a more restrictive definition of a dietary supplement.

Labeling and promotion issues should also be addressed so that health claims are substantiated by scientific studies that have been published in peer reviewed journals and/or carried out and reviewed by experts in the field.

The emphasis should be on demonstrating product safety (as required of herbal medicines in Germany, for example), quality, efficacy, and benefit. The practice of clinical nutrition therapeutics (and herbal medicine) should be regulated in ways comparable to other disciplines and specialties in traditional and complementary medicine in the U.S.