

January 9, 2003

Dear Stakeholder:

I am pleased to announce that the Food and Drug Administration (FDA) is undertaking an Initiative on Consumer Health Information for Better Nutrition to provide consumers with more and better information about conventional foods and dietary supplements to help them make sound dietary decisions and improve their health. Under this initiative, FDA will encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products. At the same time, FDA will work toward eliminating bogus health claims by dietary supplement marketers by stepping up our enforcement in this area.

Secretary of Health and Human Services Tommy G. Thompson has emphasized that "By putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims." FDA's initiative has three major components:

First, the Agency is issuing a new guidance document describing the circumstances in which it will decline to initiate enforcement action with respect to qualified health claims made in the labeling of conventional foods. Formerly, such claims were authorized only for dietary supplements. Any such claims must be pre-approved by FDA and meet the "weight of the scientific evidence" standard, including support by a credible body of scientific data.

Second, FDA is strengthening enforcement of dietary supplement rules. The Agency is committed to carrying out the intent of Congress in the Dietary Supplement Health and Education Act of 1994. Towards that end, FDA recently issued a report outlining its enforcement strategy against false or misleading claims about dietary supplements. On December 16, 2002, FDA took its first enforcement action under the Consumer Health Information for Better Nutrition Initiative. This involved the seizure of a dietary supplement promoted as a "natural" treatment for viruses, including the herpes virus, and for "cold and flu protection." FDA charges that the supplement is an unapproved, and therefore illegal, new drug because it is promoted to treat or prevent specific diseases and conditions.

And third, the Agency is establishing a Task Force on Consumer Health Information for Better Nutrition to develop a framework to help consumers obtain accurate, current, and science-based information about conventional food and dietary supplements. The work of this Task Force will include the development of additional guidance on how the "weight of the evidence" standard will be applied, as well as the development of regulations that will give these principles the force and the effect of law.

Our mission at FDA is to improve health outcomes for consumers throughout the United States. Through this Better Health Through Better Information Initiative, we are committed to improving opportunities for consumers to get scientifically accurate information about the health consequences of the foods they consume. To build consumers' trust in health claims, FDA is redoubling its enforcement efforts against those who make false and misleading claims for their products.

A Notice of Availability about FDA's guidance on qualified health claims went on display on December 18, 2002 at the office of the *Federal Register*. Both the notice and the guidance itself are available online at <http://www.fda.gov/ohrms/dockets/default.htm>.

FDA's Dietary Supplement Enforcement Report is available on FDA's website, <http://www.fda.gov/>, as is the document "Consumer Health Information for Better Nutrition," a brief, descriptive summary of FDA's entire consumer health information initiative.

FDA advises consumers to consult a health professional before taking dietary supplements. Information about dietary supplements is available on FDA's website at <http://www.cfsan.fda.gov/~dms/supplmnt.html>. Consumer advice from FDA about purchasing medicines on-line may be found at <http://www.fda.gov/oc/buyonline/default.htm>.

Enclosed is a copy of the Press Release announcing this initiative.

Sincerely,



Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure