

**U.S. Food and Drug Administration****CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**

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# **FDA IMPLEMENTS ENHANCED REGULATORY PROCESS TO ENCOURAGE SCIENCE-BASED LABELING AND COMPETITION FOR HEALTHIER DIETARY CHOICES**

## **TODAY'S ACTION**

To confront the growing epidemic of obesity and obesity related diseases in America, FDA will implement a review process for qualified health claims to help consumers obtain accurate, up-to-date, and science-based information about the health consequences of the foods they consume. Today's report is one product of the "Better Health Information for Better Nutrition" initiative, which was launched in December 2002.

## **BACKGROUND ON FDA'S INITIATIVE ON BETTER HEALTH INFORMATION FOR BETTER NUTRITION**

The United States' food supply is as safe as any in the world, but there is a growing evidence that Americans are not using it to their best advantage. Our population is getting heavier -- according to a recent study, by an average per capita gain of 1.8 - 2.0 pounds each year over the past decade-- and the trend has dramatic consequences for the U.S. public health. According to some estimates, at least 300,000 deaths each year are caused by heart disease, diabetes, cancer, and other serious chronic diseases that are associated with unhealthy nutritional choices and lack of physical activity.

To confront the need for further action to help Americans improve their diet, in December 2002 FDA launched a "Consumer Health Information for Better Nutrition" initiative with two main parts. First, a Task Force of experts in nutrition and consumer information from the FDA, the Federal Trade Commission, and the National Institutes of Health worked with public input to develop recommendations on how to give consumers access to more truthful, non-misleading, and readily understandable information about the health impact of the food they eat. The agency believes that helpful, scientifically accurate, carefully and expertly reviewed qualified health claims on food packages would influence shopping choices, and thereby encourage food firms to compete on the health effects of their products, rather than merely their taste, price or ease of use. Based on Task Force recommendations, FDA is announcing a new initiative to enable consumers to get additional, FDA-approved information on the health consequences of their food choices.

Second, in collaboration with the FTC, the FDA intensified enforcement of public health laws in order to protect consumers against false and misleading claims about the health benefits of dietary supplements. These products, which are used by an estimated 158 million Americans, have been in recent years frequently labeled with highly misleading claims about their alleged health effects. In addition to increased cooperation with other law enforcement agencies, the FDA announced as part of the December initiative the list of dietary supplement claims, such as effectiveness for mental retardation, Down's Syndrome and other serious or life-threatening diseases, that are subject to especially vigilant FDA surveillance. FDA and FTC expect that this enhanced collaboration to protect consumers from misleading health claims may provide valuable lessons and experience for how the agencies can work together in other areas to help assure that consumers have access to accurate information about how they can protect and promote their health.

### **NEW FDA REGULATORY PROCESS TO IMPROVE INFORMATION ON THE HEALTH CONSEQUENCES OF DIETARY CHOICES**

FDA will implement an interim process for review of qualified health claims in food labeling that will allow food products to carry FDA-approved health claims, provided that FDA determines that the claims are scientifically supportable and that they are presented in a way that accurately conveys any scientific uncertainty about the claims. These procedures reflect the deliberations of the interagency Task Force, which conducted six months of intensive work to develop its recommendations.

Specifically, for a qualified health claim to appear on a food product:

- Claims must go through an FDA review process.
- The review of the claim may include an expert evaluation of the supporting scientific evidence for the claim, often with assistance of the Evidence-Based Practice Centers of the Agency for Healthcare Quality Research (AHRQ).
- The claim will include language that accurately conveys to consumers how much scientific evidence supports the claim. FDA is conducting further consumer studies to make sure the language used in the claims is well understood by consumers.

The goal of this interim FDA review process is to stimulate the flow of meaningful, up-to-date information to consumers about the health consequences of their dietary choices, and to stimulate competition among food producers to improve the healthfulness of their products. The task force recommended an interim procedures and an interim ranking system for scientific data that the agency will begin to use on September 1, 2003, to systematically evaluate the scientific evidence supporting qualified health claims. It also presents three possible longer-term options for regulating health claims, which the agency intends to develop through rulemaking about one year from now.

In this interim period, the FDA will prioritize health claims for review based on the potential significance of the product's health impact on a serious or life threatening illness and the strength of evidence in support of the claim. In particular, the health claims that will be evaluated first include:

- The benefits of eating at least several servings a week of foods high in omega-3 fatty acids, including certain oily fish like ocean salmon, tuna and mackerel, for reducing the

risk of heart disease.

- The benefits of substituting nuts for other sources of saturated-fat-containing protein to help reduce the risk of heart disease.

Health messages that producers may now use include:

- The benefits of eating five to nine servings a day of fruits and vegetables for reducing the risk of some cancers and other chronic illnesses.
- The benefits of replacing solid fats that are high in saturated and trans fats with vegetable oils containing unsaturated fats for reducing the risk of heart disease.

In its evaluation of the scientific evidence in support of a health claim, the FDA will use a four-point scale starting with level "A" that designates *unqualified* health claims supported by evidence that meets the current standard of "significant scientific agreement." The scientific ranking of *qualified* health claim would start with level "B" and include such qualifying language as "...although there is scientific evidence supporting the claim, the evidence is not conclusive." The next level of claim, "C", would use such qualifying language as "evidence is limited and not conclusive." The lowest level of claim, "D," would be qualified by such statements as "Very limited and preliminary scientific research suggests that... FDA concludes that there is little scientific evidence supporting this claim."

The report's action plan also includes the following activities and measures:

- The report presents three possible options for regulating qualified health claims.
- Augmentation of the agency's resources for the review process through review assistance by the Agency for Healthcare Research and Quality (AHRQ), establishment of new FDA expert positions on nutrition-associated activities, contracting the services of two private scientific centers, and restructuring certain FDA food programs.
- Research agenda for studies exploring consumers' ability to understand the different levels of science supporting the qualified claims, and finding the appropriate words, symbols or other means to convey the differences.
- Timeline for the initiative's main activities from June 30, 2003 to June 1, 2004.

To support these efforts, FDA has reorganized activities in Applied Nutrition in its Center for Food Safety and Applied Nutrition to enhance support for getting better information to consumers. FDA's Office of the Commissioner is also devoting significant new effort and staff to issues related to healthy behavior and risk communication. FDA is also establishing collaborative programs with the Federal Trade Commission and the National Institutes of Health to provide assistance for these efforts.

## **INCREASED ENFORCEMENT VIGILANCE TO HELP ASSURE ACCURACY OF HEALTH CLAIMS**

In addition to the document prepared by the Task Force, the FDA released a report on its enforcement activities since the mid-December announcement of FDA's enhanced enforcement efforts involving dietary supplements, to further improve information available to consumers. The report shows that by July 1, 2003, FDA had:

- issued 73 warning letters and Cyber letters to marketers of dietary supplements,
- seized products worth almost \$9 million,
- refused to allow the importation of 368 shipments of dietary supplements, and
- supervised the voluntary destruction of \$515,000 worth of dietary supplements promoted with unsubstantiated structure/function claims.

By comparison, in 2001 FDA issued 21 warning letters and seized unlawful dietary supplement products worth \$2 million.

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