

Abstract: The Food and Drug Administration (FDA) recently announced changes in its control of health claims on conventional food and dietary supplements. The new policy requires manufactures provide "the weight of scientific evidence" when petitioning for the placement of a claim on product labels. Previously the requirement for submission was "significant scientific evidence" as reviewed by expert panels. The main purpose of such a policy change is to encourage firms to make accurate, science-based claims about the health benefits of their products. This policy change aims to help consumers prevent disease and improve their health through sound dietary decisions using improved nutrition information. The objectives of this study are to analyze in greater detail how this new policy differs from the previous process and examine potential effects on the opportunity for functional foods and consumer well-being. The new submission requirement of scientific agreement on health claims is likely to be less restrictive than the previous regime, which should facilitate more qualified health claims on product labels. This will provide greater opportunities for firms to communicate the health benefits of their functional foods to consumers. Consumer welfare will improve if they use such information, understand diet-health links, and adapt consumption behavior. However, welfare improvements are conditional on the truthfulness of such claims. The provision of "emerging" health claims on functional foods may promote confusion. Thus FDA must ensure that the new policy, though it requires less scientific evidence, does not result in more misleading or false health claims.

What is a Functional Food?
"Any modified food or food ingredient that may provide a health benefit beyond the traditional nutrient it contains"

Three Types of Health Claims Currently Allowed by FDA

NLEA Authorized Health Claims

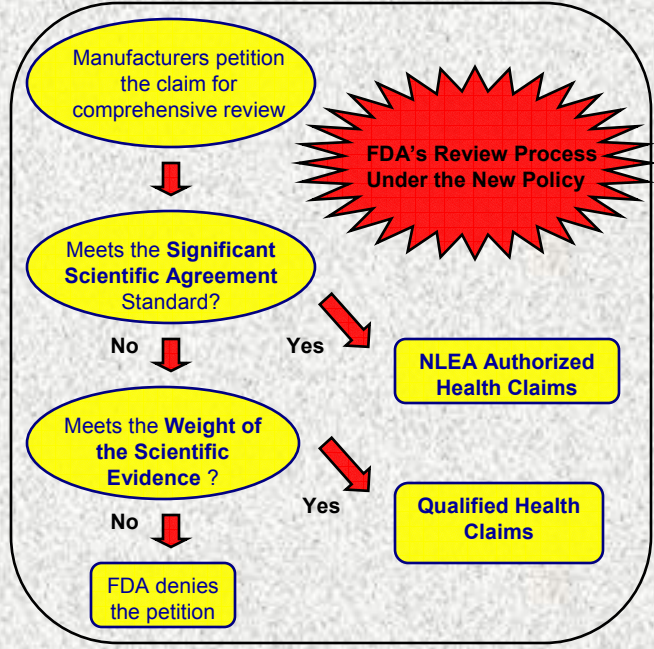
- Following the Nutrition Labeling and Education Act (NLEA) 1990
- Based on the totality of the publicly available scientific evidence *using the significant scientific agreement standard*
- Currently, there are 12 claims under this category
- "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease"

Health Claims Based on Authoritative Statement

- Following the Food and Drug Administration Modernization Act (FDAMA) 1997
- Based on an *authoritative statement* from a scientific body of the US government or the National Academy of Sciences
- Currently, there are 2 claims under this category
- "Diet containing foods that are good source of potassium and low in sodium may reduce the risk of high blood pressure and stroke"

Qualified Health Claims

- A result of the U.S. Court of Appeal for the D.C. Circuit 1999 decision in the case of *Pearson v. Shalala*
- Based on the *weight of scientific evidence*
- Used to be allowed only for dietary supplements, but now will be allowed for foods
- "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive"



Significant Scientific Agreement vs. Weight of Scientific Evidence

- Key difference Between Existing and New Health Claim Policy
- Significant Scientific Agreement:** The validity of the relationship is not to be reversed by new and evolving science. Must be agreed among qualified experts that the claim is valid
- Weight of Scientific Evidence:** The scientific findings in support of the claim outweigh the scientific evidence against the claim. Does not need to meet the significant scientific agreement standard

What is a Health Claim?
"It is a claim approved by FDA describing a relationship between a food substance and a disease or health related condition"

Potential Impact of New Policy on Manufacturers and Consumers

More health claims should be allowed
4 already approved qualified claims on dietary supplements will now be allowed on foods

More functional foods marketed / available to consumers. Note that all claims need to be pre-approved by FDA

More information available for making better decisions to maintain or improve health

Consumer Groups
Raise issues such as more false and misleading claims will likely arise because of the new less restrictive policy

FDA's Reaction
FDA task force to evaluate the new policy and issue guidance on qualified health claims and how to strengthen enforcement