

claims under consideration, we are seeking emergency approval of the proposed study in order to provide needed consumer data in time to assist the agency in developing new regulations for qualified health claims.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Health Claim Disclaimers on Foods

FDA is requesting OMB approval of an experimental study of health claims and disclaimers on food labels to help the Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for qualified health claims. Several possible approaches to implementing this qualified health claim scheme that differ in terms of the specific language and form of disclaimers used to convey level of scientific certainty are evaluated in terms of the ability of the proposed approach to accurately convey the actual level of scientific uncertainty for the stated claim.

The recent report of the FDA Task Force (Consumer Health Information for Better Nutrition Initiative Task Force Final Report, July 10, 2003) describes a four-level rating scheme for evaluating petitioned claims (consisting of unqualified claims that meet the standard of significant scientific agreement as defined by NLEA and three levels of qualified claims supported by decreasing levels of scientific evidence). The proposed consumer research is designed to test approaches to conveying levels of scientific uncertainty through the use of disclaimers that are linked to this four-level rating scheme for petitioned health claims.

The proposed study is intended to evaluate the effectiveness of several possible options for communicating the strength of scientific evidence for a given health claim across a range of health claims of varying scientific certainty. The evidence should provide empirical support for possible policy decisions about the need for disclaimers to minimize consumers' misunderstanding and misapplication of qualified health claims and the optimal language and the form such disclaimers should take. The impact of disclaimers is examined across a range of measures that capture what is conveyed about the state of scientific certainty for the claim as well as the impact of the qualified health claim on attributions about the food product that displays the claim.

FDA will conduct an experimental study using shopping mall intercept samples. The mall intercept methodology allows controlled presentation of visual materials, experimental manipulation of study materials, and the random assignment of participants to experimental conditions. The experimental manipulation of label conditions and random assignment to conditions allows for statistical estimates of the effects of different approaches to conveying level of scientific support and allows quantitative comparisons of the effectiveness of different forms and wording options for health claim disclaimers. Random assignment ensures that mean differences between conditions can be tested using established techniques such as analysis of variance and multiple regression analysis to yield statistically valid estimates of effect size.

The study design is based on the controlled presentation of realistic product labels that carry health claims for four nutrient/disease health claims. The four health claims that are tested vary in terms of the degree of scientific evidence underlying the health claim. Label conditions consist of different forms and specific wordings for disclaimers that accompany the nutrient/disease health claim as well as various control conditions that assess how consumers view the product and the scientific evidence in the absence of an explicit health claim on the product label.

Participants will be recruited using standard mall intercept methods,

implemented in 6 geographically dispersed shopping malls. Participants are adults, aged 18 and older who do half or more of the grocery shopping for their household. Each site will have the same number of replicates of the experimental design that include all counterbalancing factors.

Four different schemes for communicating strength of science are tested: Point-Counterpoint (claim, followed by disclaimer), Embedded language (disclaimer first), Report Card (A-D letter ratings) and Graphic (graphic device to illustrate the rating scheme). Each scheme adopts the four-level strength of science ranking system described in the Interim Guidance.

The study includes four control conditions, representing important types of label statements and label users that constitute benchmarks for assessing the direction and magnitude of effects due to communications about the strength of scientific evidence for the health claims: (1) "Tombstone" control with no nutrient content or health claim, (2) nutrient content claim, but no health claim, (3) "full information control" in which the participant is provided with a summary of the scientific evidence for the claim prior to observing food labels and (4) expert controls, based on separate information gathered from nutrition experts knowledgeable about the diet-disease relationship.

The key measures for this study are the perceived strength of science for the claim that is conveyed by the label condition and product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings) that identify the practical impact of the product label.

FDA will use the information from this study to guide the development of regulatory policy options related to qualified health claims. The agency acknowledges the lack of empirical data about how consumers understand and respond to statements they see in product labeling. The information gathered in this study can be used by the agency to assess likely consumer responses to various options for qualifying health claims based on varied levels of scientific evidence.

FDA estimates the burden of this collection of information as follows: