

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101****[Docket Nos. 94P-0390 and 95P-0241]****Food Labeling: Health Claims; Availability of FDA Report of Effects of Food Label Health Claim Statements; Reopening of Comment Period****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Consumer Impacts of Health Claims: An Experimental Study" (the FDA Study). The FDA Study is relevant to issues under consideration in the rulemaking that FDA instituted on December 21, 1995, with a proposal to amend its regulations on nutrient content and health claims to provide greater flexibility in the use of these claims on food products. FDA is adding this report and two related studies on abbreviated health claim statements to the administrative record of that rulemaking. In addition, FDA is reopening the comment period for the December 21, 1995, proposed rule (60 FR 66206) to provide interested persons with an opportunity to obtain the FDA Study and to submit comments.

DATES: Written comments by March 10, 1997.

ADDRESSES: Submit written requests for single copies of the FDA Study "Consumer Impacts of Health Claims: An Experimental Study" and the studies submitted by The Quaker Oats Co. to the contact person listed below. Send two self-addressed adhesive labels to assist in processing your request. A copy of the FDA Study and received comments are available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA Study may also be viewed on the FDA World Wide Web site (<http://www.fda.gov>) by selecting Foods, then Food Labeling from the menus presented. Submit written comments to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan S. Levy, Center for Food Safety

and Applied Nutrition (HFS-727), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-9448.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 21, 1995 (60 FR 66206), FDA published a proposed rule, entitled "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims" (the December 1995 proposal), to amend its regulations on nutrient content and health claims to provide greater flexibility in the use of these claims on food products. The agency proposed to permit the use of shortened versions of authorized health claims and to eliminate some of the required elements of these claims. The proposed rule provided a 90-day period for public comment. The agency extended the comment period for an additional 120 days on March 22, 1996. The comment period closed on July 18, 1996.

FDA has recently completed research on the effects of food label health claim statements on consumers. This research bears directly on the issues involving health claims that were raised in the December 1995 proposal. FDA believes that it may be appropriate to consider that research in developing a final rule in the subject rulemaking. Therefore, FDA is placing the FDA Study on this research in the docket for the December 1995 proposal and is reopening the comment period on the proposal to provide an opportunity for interested parties to comment on the FDA Study. FDA is providing 45 days so that interested parties have sufficient time to obtain the study and submit comments on it.

Shortly after publication of the December 1995 proposal, FDA published a proposed rule to authorize a health claim on the association between oat bran and oatmeal and the risk of coronary heart disease (61 FR 296, January 4, 1996). In response to that proposal, FDA received a comment from The Quaker Oats Co. that included two studies on the use of abbreviated health claims. Inasmuch as shortened health claims were a primary focus of the December 1995 proposal, the agency has submitted these studies to Docket Number 94P-0390 for consideration in the rulemaking on the December 1995 proposal. Interested parties may submit comments on these studies during the reopened comment period.

I. The FDA Study**A. Background**

The final report of the Keystone National Policy Dialogue on Food,

Nutrition, and Health (Ref. 1) reviewed several issues raised by the food labeling regulations that FDA adopted in response to the Nutrition Labeling and Education Act of 1990. This report identified issues related to health claims as among those most in need of study. The report also noted the lack of research about how consumers respond to health claims on food labels and raised a number of specific questions about the relative effectiveness of specific language contained in FDA model health claim statements. The report strongly recommended that consumer research be conducted to evaluate the impact of alternate forms of health claim statements on food labels.

The goal of the regulations governing health claims, to help consumers achieve a healthier diet, is one with which virtually everyone agrees, but there are many viewpoints, and no small controversy, about how to best achieve it. Uncertainty about how best to structure health claims arises from the lack of experience with this type of claim, but it also reflects the diversity of opinion about how health claims will affect consumer behavior.

The Department of Health and Human Services provided funds to FDA to conduct research on the effect of health claims on consumer understanding and behavior, so that the agency would have a firm empirical basis to evaluate the requirements that it has adopted and any revisions that it may contemplate. The agency designed a study to investigate the effects of different versions of health claim statements on a range of variables chosen to represent some of the different possible effects of health claims.

A preliminary focus group study evaluated a number of proposed health claim statements developed by the Keystone Dialogue as alternatives to FDA's model health claim statements (Ref. 1, pp. 141 to 150). The results suggested that FDA's model claims could be improved, and it highlighted some basic issues underlying consumer reactions. Central to consumer reactions to health claims was the credibility and authoritativeness of the claims. The brevity of a claim was seen by consumers as a significant element of the effectiveness of health claims, but preferences for brevity seemed to depend on the degree of familiarity (i.e., amount of prior knowledge) with the given diet/disease relationship. The focus group results also emphasized the importance of looking at several different kinds of health claims, because consumer reactions were noticeably different depending on familiarity with the claim. FDA used the results from the

focus groups to identify the independent variables for a larger study.

B. Study Design

The FDA Study was a shopping mall intercept study. Subjects were primary food shoppers recruited at a mall with central interviewing facilities at eight sites around the country. The sample size was approximately 175 persons per site (total sample size was 1,403 persons), with quotas for age and education to ensure that the full range of population characteristics were represented in the sample. Subjects were randomly assigned to an experimental condition. In the central interviewing facility, an interviewer administered the experimental protocol in a 20 to 25 minute session. Subjects were presented, one at a time, with realistic product packages. The packages were of typical size and organization for the particular type of product, including front and back label information appropriate for the product category. The product types and health claims represented included: Cheese lasagna/saturated fat and cholesterol and risk of coronary heart disease; yogurt/calcium and osteoporosis; and breakfast cereal/folic acid and risk of neural tube defects.

The presentation style, authority, and brevity of the health claim were experimentally manipulated. Each product label seen represented a cell in the experimental design. The order of presentation of the products and the type of health claim were counterbalanced to avoid confounding effects. A series of questions about each product measured purchase intentions and communication effectiveness of the product label (e.g., perceived health benefits, compellingness), as well as personal and household characteristics. Information search behavior was observed and recorded.

C. Conclusions

The results of the FDA Study (Ref. 2) show that shorter claims are more effective than longer claims, that endorsed health claims have liabilities compared to nonendorsed claims, and that splitting claims between the front and back label makes little difference. The results also show that the ability of health claims to accurately communicate health information about a product appears to be fairly limited and involves tradeoffs between different kinds of valid health information.

II. The Quaker Oats Co. Studies

The Quaker Oats Co. submitted reports of two studies pertaining to the use of abbreviated health claim

statements as a comment to Docket No. 95P-0197 (61 FR 296). The consumer research in the first report, entitled "Quaker Oatmeal On-Pack Health Claim Survey," provided data on the question of whether consumers would read the full claim if only an abbreviated claim appeared on the front of the label (Ref. 3). The data were based on a national telephone survey of 301 consumers. The respondents were asked about four types of new highlighted messages on the front of a package of breakfast cereal (health or nutrition; improvements to the product; price; special offers or rebates). The key questions concerned how likely respondents would be to read each of the four types of messages on the front of a package, and, if they noticed a new highlighted message on the front of the package that was about health benefits and that stated that additional information could be found on the back of the package, how likely they were to read the additional information.

The second report, entitled "Consumer Perception Study of a Statement Related to Heart Disease on the Label of Quaker Oats," presented consumer research comparing an abbreviated oatmeal claim ("A diet high in oatmeal may help reduce the risk of heart disease.") with a full fiber-heart disease health claim ("Diets low in saturated fat and cholesterol and high in grains, fruits and vegetables that contain fiber, particularly soluble fiber, may reduce the risk of heart disease, a condition associated with many factors.") (Ref. 4). The data were from a national shopping mall intercept study of 826 consumers. Participants saw one of three mocked-up cereal packages that contained the abbreviated claim, the long claim, or no claim (control condition).

The report stated that the presence of either health claim, compared to the control condition, increased the number of participants who recognized that a diet high in oatmeal may help reduce the risk of heart disease. There were no significant differences in terms of the impact of the claims on consumers' perceptions of the product or their beliefs about the diet-disease relationship.

III. Comments

Interested persons may by March 10, 1997, submit to the Dockets Management Branch (address above) written comments regarding the studies being added to this docket. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in

brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. The Keystone Center, "The Final Report of The Keystone National Policy Dialogue on Food, Nutrition, and Health," Keystone, CO and Washington, DC, March 1996.

2. Food and Drug Administration, U.S. Department of Health and Human Services, "Consumer Impacts of Health Claims: An Experimental Study," Washington, DC, December 1996.

3. The Quaker Oats Co., "Quaker Oatmeal On-Pack Health Claim Survey," Chicago, IL, March 1996.

4. The Quaker Oats Co., "Consumer Perception Study of a Statement Related to Heart Disease on the Label of Quaker Oats," Chicago, IL, November 1995.

Dated: January 17, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-1785 Filed 1-23-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01-96-002]

RIN 2115-AE47

Drawbridge Operation Regulations: Mystic River, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating rules for the S99 Alford Street Bridge over the Mystic River in Boston, Massachusetts. Additionally, the regulations governing the Boston and Maine Bridge and the General Lawrence Bridge will be removed because both bridges have been replaced with fixed bridges. The owner of the S99 Alford Street Bridge has requested that an 8 hour notice for openings be provided from November 1 through March 31, between 11 p.m. and 7 a.m. This change is expected to provide for the needs of navigation and relieve the bridge owner of the burden of crewing the bridge at night during the winter months.

DATES: Comments must be received on or before March 25, 1997.