

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0507]

Agency Emergency Processing Request Under OMB Review; Experimental Study of *Trans* Fat Claims on Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is an experimental study of *trans* fat claims on foods to evaluate the effects of various possible disclosure requirements to help consumers understand and apply *trans* fat claims that they might see on food products. The study is intended to estimate the communication effectiveness of these disclosure requirements in realistic label usage situations for a range of products that may bear *trans* fat claims.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in Federal Register*]. FDA is requesting approval of this emergency processing by [*insert 30 days after date of publication in the Federal Register*].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received,

OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is critical to the agency’s mission of regulating food labeling and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320). Consumer education activities are needed to ensure the successful implementation of the regulation mandating disclosure of the *trans* fat amount on food label. Before these activities can be completed, it is necessary to resolve questions about possible accompanying disclosure requirements for *trans* fat nutrient content claims. Delays in resolving this issue will undercut the effectiveness of these activities and reduce the value of mandatory *trans* fat disclosure. For this reason, the use of normal clearance procedures would be likely to prevent or disrupt this collection of information.

FDA invites comments on: (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.

An Experimental Study of *Trans* Fat Claims on Foods

FDA is requesting OMB approval of an experimental study of *trans* fat claims on food products to help FDA’s Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat claims on foods. In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA published an advance notice of proposed rulemaking entitled “Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements.” The document announced that the agency was seeking information about possible disclosure requirements to accompany nutrient content claims about *trans* fatty acids to help consumers make heart-healthy food choices. The proposed study is intended to evaluate the ability of several such disclosure requirements to enable consumer heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such disclosures and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from shopping mall intercept and Internet panel samples to evaluate how consumers understand and respond to claims on products with differing fatty acid profiles and possible disclosure requirements with those claims. The distinctive features of Internet panel and shopping mall methodologies for the purpose of this study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of

the various possible disclosure statements label statements while controlling for individual differences. Random assignment ensures that mean differences between conditions can be tested using well known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. By implementing the study in a large nationally representative consumer panel with 600,000 households or in a geographically diverse set of shopping malls, the generalizability of the findings to a large fraction of the general population is also ensured.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to 1 of the 126 experimental conditions consisting of fully crossing 7 footnote disclosure conditions, 3 product types, 3 fatty acid profiles and 2 prior knowledge conditions.

Respondents will provide background information and respond to package labels that contain the variations of label statements to be tested. Key measures for the study are product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings).

FDA will use the information from the study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this study can be used by the agency to assess likely consumer responses to various disclosure requirements for nutrient content claims.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Internet survey	2,520	1	2,520	.4	1,008

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					1,008

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We anticipate that all statistical tests will collapse across the three product categories. We estimate that 20 subjects per cell, 2,520 subjects in all, will provide adequate power to identify small to medium size effects (i.e., $r = .15$ to $.30$) for all main effects and first order interactions with power = $(1 - \beta)$ well in excess of $.80$ at the $.05$ significance level. Power for second and third order interactions will necessarily be smaller, but even for third order interactions, statistical power will be $=.80$ at the $.10$ significance level.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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