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.

[FR Doc. 03–28194 Filed 11–7–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0506]

Agency Emergency Processing Request Under Office of Management and Budget Review; Experimental Study of Possible Footnotes and Cuing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel

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 possible footnotes and cuing schemes to help consumers understand and apply quantitative *trans* fat information they might see on the Nutrition Facts panel (NFP) of a food product. The study is intended to estimate the communication effectiveness of these disclosure requirements in terms of the ability to help consumers make heart-healthy product decisions in realistic label usage situations for a range of products that will disclose quantitative *trans* fat information.

DATES: Fax written comments on the collection of information by December 10, 2003. FDA is requesting approval of this emergency processing by December 10, 2003.

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 necessary 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 accompanying footnotes and cuing schemes. Delays in resolving this issue will undercut the effectiveness of these education 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 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 Possible Footnotes and Cuing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel (NFP)

FDA is requesting OMB approval of an experimental study of possible footnotes and cuing schemes to help consumers interpret quantitative *trans* fat disclosure on the NFP to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure. 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,'' stating that the agency is seeking information about whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use disclosed information on the label to make healthy food choices. The proposed study is intended to evaluate the ability of several possible footnotes and cuing schemes to enable consumer heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such requirements 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 possible footnotes and cuing schemes. The distinctive features of internet panel and shopping mall methodologies for the purpose of the 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 footnotes and cuing schemes while controlling for individual differences between subjects. 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 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 one of the 42 experimental conditions consisting of fully crossing seven

possible footnotes/cuing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the study to evaluate regulatory and 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 to estimate consumer comprehension and behavioral impact of various footnotes and cuing schemes intended to enable better understanding of quantitative *trans* fat information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

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	1,004
Total					1,004

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

We estimate that 60 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0509]

Agency Emergency Processing Under Office of Management and Budget Review; Experimental Study of Health Claim Disclaimers 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 health claims on food product labels to evaluate the communication effectiveness of various possible labeling statements (i.e., disclaimers) to convey differing levels of scientific support for health claims. The study examines the communication effectiveness of disclaimers in realistic label use situations for a range of health claims and associated food products that may bear such health claims.

DATES: Fax written comments on the collection of information by December 10, 2003. FDA is requesting approval of this emergency processing by December 10, 2003.

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 (44 U.S.C. 3507(j) and 5 CFR 1320.13). The information is critical to the agency's mission of regulating food labeling. Currently FDA is operating under interim procedures for reviewing qualified health claims on conventional foods and dietary supplements (''Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements,'' that published in the **Federal Register** of July 10, 2003 (68 FR 41387–41390)). This interim approach was necessitated by various developments since the passage of the Nutrition Labeling and Education Act (NLEA), including successful legal challenges based on the First Amendment. The interim procedures provide guidance to industry regarding how the agency will respond to qualified health claims until the agency can promulgate notice-and-comment rulemaking. However, guidance documents do not establish legally enforceable responsibilities and are intended only as recommendations.

The interim procedures strain the agency's limited resources for reviewing qualified health claims. Qualified health claims greatly increase the number of potential health claims and as a result the agency anticipates a far greater number of health claim petitions. The agency included criteria for prioritizing petitions in order to maximize the public health benefit of its interim qualified health claim procedure, which will necessitate delays for some petitions. The interim guidance also creates uncertainty for industry, since qualified health claims are permitted through a letter of enforcement discretion, and are not authorized through a regulation. This is likely to inhibit some companies from submitting petitions during the interim period. FDA prefers that this interim period be as short as possible.

Consumer data are important to the development of new regulations for health claims. A central consideration in the development of a new regulatory framework for qualified health claims is the importance of ensuring that such claims can be made in a way that is not misleading to consumers. The agency recognizes that it is unknown whether consumers can distinguish between differing levels of scientific support and there are no consumer data currently available to assess the effectiveness of wording options proposed for conveying the different levels. The interim guidance relies on limited prior experience under a temporary policy of enforcement discretion, using ad hoc health claim disclaimers.

Given the uncertainties and constraints inherent with interim guidance and the absence of relevant consumer data to address questions raised by the new approaches to health