

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 <sup>1</sup>

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

<sup>1</sup> 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  $\approx .80$  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