VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: April 14, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0486]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Health Claims on Food Packages

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 20, 2005.

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 written 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study of Health Claims on Food Packages

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)).

To help consumers reduce their risk of disease and improve their health by making sound dietary decisions, in the **Federal Register** of November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on various issues related to health claims on conventional food and dietary supplement labels. One of the issues that FDA raised in the ANPRM related to whether the wording of a health claim needs to refer to the substance (a component of food, e.g., a nutrient) that is the basis of the claim. (Hereinafter, the term ''health claim'' will refer only to a claim meeting the standard of significant scientific agreement or, in other words, an FDA- authorized claim.) For instance, in the example of the calcium-osteoporosis claim (''Calcium may reduce the risk of osteoporosis''), FDA currently requires that the substance that is the basis of the claim (in this case, calcium) be included in the wording of the claim (21 CFR 101.72). The requirement that the substance in a health claim be included in the wording of the claim was motivated by FDA's experience that most substances that are the subject of an authorized health claim are, like calcium, substances that can be found in a number of foods. Therefore, FDA requires that health claims refer to the common substance to assist consumers in their understanding of the nature of the diet-health relationship and, more importantly, to help consumers recognize that they can construct healthy diets by using a variety of foods that contain the substance.

FDA requests comments on the usefulness of such statements (e.g., ''Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis'') versus ''food-specific'' claims that do not specify the food component (e.g., ''Yogurt may reduce the risk of osteoporosis''). How consumers respond to the two kinds of statements can suggest how the explicit mention of a food component in a claim affects dietary choices which, in turn, informs any policy initiative(s) that FDA may undertake in the future to provide information to consumers to help them make informed food choices.

The purpose of the proposed collection of information is to enhance FDA's understanding of consumer responses to health claims and inform any policy initiative(s) that FDA may undertake in the future. The information will be used to assess what differences, if any, the inclusion of the food component in a health claim makes in the following areas: (1) Consumer recognition of the food component underlying a diet-disease relationship; (2) consumer recognition that, in addition to the food product that carries the claim, there are other foods from which they can obtain the food component; and (3) consumer perceptions of, and attitudes toward, the food.

The proposed collection of information is a controlled randomized experimental study. The study will use a 6 x 3 within-subjects design (6 front-panel health claims/health messages x 3 diet-disease relationships), with participants randomly assigned to experimental conditions. In total, the study will examine 18 experimental conditions (6 front-panel health claim/health message conditions x 3 diet-disease relationships), each condition is a combination of a front-panel condition and a diet-disease relationship.

The term ''health message'' refers to nutrient content claims, structure/function claims, and dietary guidance statements. Prior knowledge of foods, components of food (e.g., nutrients), and risks will be measured; such prior knowledge will serve as covariates in the analysis. There are two independent variables, type of front-panel health claim/health message and type of diet-disease relationship. Health claim/health message conditions include the following items:

1. A ''food-specific'' health claim, e.g., ''Yogurt may reduce the risk of osteoporosis;''
2. A ''nutrient-specific'' health claim, e.g., ''Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis;''
3. A nutrient content claim, e.g., ''a good source of calcium;''
4. A structure/function claim, e.g., ''Helps promote bone health;''
5. A dietary guidance statement, e.g., ''Dairy products may reduce the risk of osteoporosis;'' and
6. No health claim/health message.

Claims on food labels must be truthful and nonmisleading as required under sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n) and 343(a)(1)).

Health messages other than the two health claims are included solely for methodological purposes. The ''no health claim/health message'' condition is included to examine what consumers already know about nutrients or food sources, even when neither of them is mentioned on a label. Health messages are frequently found on food product packages and provide consumers various amounts of information about

food products and their relationships to health. Whether consumer responses to these health messages are consistent with their responses to the two health claims will help generalize the findings. An examination of response differences between health messages that mention (e.g., a nutrient content claim) or do not mention (e.g., a structure/function claim) a nutrient or food source, and between these health messages and the two health claims in question can help validate any effects observed between the two health claims. This validation will in turn enhance the external validity of the findings between the ''food-specific'' and ''nutrient-specific'' health claims. We emphasize, however, that the inclusion of examples of structure/function claims, nutrient content claims, and dietary guidance statements does not in any way suggest or imply any new or impending change in regulatory actions regarding these messages.

The study proposes to include three examples of diet-disease relationships: (1) Yogurt-calcium-osteoporosis, (2) orange juice-potassium-hypertension, and (3) bread-''lysoton''-diabetes. Lysoton is a fictitious substance; this fictitious relationship is included for test purposes only. The study includes these particular relationships solely for the purpose of covering varying levels of consumer familiarity with the foods, nutrients, and risks and to enhance the usefulness of the study findings. We emphasize that the choice to use these particular diet-disease relationships in this study does not in any way suggest or imply any new or impending change in regulatory actions regarding the use of these health claims/health messages or the scientific basis of these relationships.

The planned universe of this experimental study is members of an Internet consumer panel, all of them are adults (18 years or older). The study will use a two-phase data collection methodology. Phase 1 is an Internet interview to ask about prior knowledge. Phase 2 is another Internet interview of the same individuals to elicit responses to experimental conditions. The two interviews will be administered at least a week apart. An understanding of the influences of prior knowledge on consumer responses will help reveal factors associated with differential responses and extend the usefulness of the findings to similar messages about other diet-disease relationships. It is necessary to collect prior knowledge information before and separately from collecting responses to health claims and health messages to minimize demand and confounding effects between prior knowledge and message responses.

Target sample size of the study is 1,060 participants who complete both interviews. Participants will be randomly assigned to the same 2 of the 18 experimental conditions in both interviews. Each of the two conditions includes a different diet-disease relationship and a different front-panel condition. Presentation order of the conditions will be counter-balanced within the sample. All front panels will be full-color and patterned after existing labels in the market. Both the front and back panels of a label will be available during the interview. Back panel information (e.g., nutrient contents) will be kept constant between front-panel conditions for a given food product.

The following key information is to be collected:

1. Responses to the experimental conditions such as perceived health benefits, substances related to the benefits, other food sources that may offer the same benefits;
2. Prior knowledge of diet-disease relationships;
3. Food purchase and consumption experience;
4. Interest in food and food purchase decisions;
5. Use of dietary supplements, special diets, and health status; and
6. Demographic characteristics.

In the **Federal Register** of December 10, 2004 (69 FR 71819), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two comments, both from the food industry.

One comment supported consumer research to enhance health message communication as a means to help consumers make sound dietary decisions. The comment suggested that to improve the quality of the study and analysis the agency should lay out the objective(s) and analysis plan of the study, consider asking about how helpful a health message is in helping consumers make food choices, consider asking respondents to read the health message on the stimulus, and consider increasing the sample size.

The agency agrees that objective, analysis plan, and pertinent measures are essential for ensuring the quality of the study. As suggested in the 60-day notice, the study is designed primarily to help understand how well food-specific health claims communicate information compared to nutrient-specific health claims, and secondarily to help understand how well health messages that include the nutrient communicate information compared to other health messages that do not include the nutrient. The agency has developed preliminary dependent measures and decision rules for analysis. In addition, the agency has added questions on the helpfulness of the messages and used a technique to ensure that participants have noticed the health message on the stimulus.

The agency is not persuaded that the sample size needs to be increased. The agency has carefully considered the sample size required for the study and consulted the relevant research. The agency has determined that the planned sample size, 1,060 in total and approximately 360 per health claim condition (120 per diet-disease relationship x 3 diet-disease relationships), is sufficient to detect meaningful main effects of repeated-measures binary responses, such as whether the responsible nutrient is recognized, and to detect interaction effects between diet-disease relationships and health message conditions.

The other comment also recognizes the importance of consumer research. It asserts, however, that the proposed study should be abandoned for two reasons. First, by testing generic and hypothetical products, brands, and marketing contexts, the agency is misconstruing its legal authority under the applicable First Amendment standards (i.e., the comment states that FDA needs to justify regulatory restrictions on the expression of any particular health claim by demonstrating alleged harms and showing that the restrictions would alleviate the harm). The comment asserts that, under such requirements, FDA's obligations are case-specific, i.e., targeted at a particular marketer with respect to a particular health claim expression. Second, the comment states that the impression consumers take away from a particular health claim cannot be evaluated in a scientifically valid or reliable manner through academic research that attempts to isolate the meaning of health claims from its context. The comment further asserts that even if valid findings are possible, they would have no validity or meaning under real world conditions. Hence, the comment argues that claims need to be tested on real product labels and in a real purchasing context.

FDA disagrees with this comment. The agency notes that the research approach mentioned in the comment, testing specific claims on specific products in specific contexts, would be appropriate if the agency's only mission were to protect consumers from harms caused by deceptive product labeling, and if the objective of the study were to

gather evidence on whether a labeling statement on a specific product marketed in a specific context could produce the alleged harm and the harm is material.

In addition to protecting consumer health from harms caused by deceptive product labeling, however, the agency's mission also calls for advancing consumer health by providing information about food products to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary choices. The study was proposed with this mission in mind and, therefore, neither intends, nor is designed to demonstrate any harm attributable to any specific health messages on any specific products. As stated in the 60-day notice, the study will hold back-panel information (e.g., nutrient contents) constant between front-panel conditions for a given food product. Furthermore, the nutrient contents of test products will meet current regulatory standards for various health messages. Therefore, by design, the study approach precludes any attempt to examine any potential harm as purported in the comment. Instead, the study approach is commonly used and accepted by researchers for the purpose of investigating communication efficacy of label stimuli.

Health messages such as health claims are intended for use by all qualifying marketers and in all qualifying products, rather than certain specific marketers or products. Hence, under the agency's regulatory regime, the study does not intend to examine specific claims on specific products in specific contexts, as individual marketers would do. Rather, the study will attempt to illustrate possible consumer responses to different types of health messages that may be found on packages of various food products. Finally, the agency notes that, despite the discordance between experimental contexts and the real world, experimental findings are widely recognized and accepted as the best available evidence to demonstrate communication efficacy.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	60	1	60	0.5	30
Invitation	2,000	1	2,000	0.02	40
Interview, Phase 1	1,060	1	1,060	0.17	180
Interview, Phase 2	1,060	1	1,060	0.25	265
Total					515

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

Prior to the administration of the interview, the agency plans to conduct pretests of the final questionnaires to minimize potential problems in administration of the interviews. The pretests, each lasting 30 minutes (0.5 hours), will be conducted in up to 3 waves, each with 20 participants. A contractor will send 2,000 e-mail invitations to recruit participants. We assume 50 percent of those contacted will agree to participate in the interviews (1,060 respondents). The interviews are expected to last 10 minutes (0.17 hours) and 15 minutes (0.25 hours) for phase 1 and phase 2, respectively.

The planned sample size per condition is approximately 120. The agency expects small main effects. Therefore, the planned sample size should yield a power of 0.8 at the 0.05 significance level.

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0470]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs For Investigational Use

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 review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by May 20, 2005.

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 written 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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Investigational Use—21 CFR Part 511 (OMB Control Number 0910–0117)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). A sponsor