DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0486]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on an experimental study to assess consumer responses to health claims on labels of conventional foods. Although the focus of the study is on consumer responses to health claims, the study also looks at their responses to other health messages to help enhance the external validity of the findings.

DATES: Submit written or electronic comments on the collection of information by February 8, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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 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 has raised in the ANPRM relates to whether the wording of a health claim needs to refer to the substance (a component of food, e.g., 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, put another way, an FDA-authorized claim.) For instance, in the example of the calcium-osteoporosis claim (''Calcium may reduce the risk of osteoporosis''), FDA requires that the substance that is the basis of the claim (i.e., calcium) be included in the wording of the claim (21 CFR 101.72). The requirement of including the substance in a health claim was motivated by FDA's experience that most substances that are the subject of an authorized health claim are substances that can be found in a number of foods (e.g., calcium) or spread throughout the food supply (e.g., saturated fat). Therefore, FDA has provided for health claims that include reference to the common substance to assist consumers in their understanding of the nature of the diet-health relationship, and more importantly so that 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 statements that expressly include the particular component of food (e.g., nutrient) that is the basis for the claim (e.g., ''Calcium-rich foods, such as yogurt, may reduce the risk of osteoporosis'') versus ''food-specific'' claims that do not include the food component (e.g., ''Yogurt may reduce the risk of osteoporosis'' (68 FR 66040 at 66047). 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. FDA, however, lacks sufficient empirical evidence to understand how consumers are likely to react to the two different kinds of health claims, has not received any such evidence in comments on the ANPRM, and is not aware of any existent evidence.

The purpose of the proposed collection of information is to help enhance FDA's understanding of consumer responses to health claims and inform any policy initiative(s) that FDA may undertake in the future to provide consumers information to help them make informed food choices. The information will be used to assess what differences, if any, the inclusion of the food component in a health claim makes in consumer recognition of the food component underlying a diet-disease relationship; 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 consumer perceptions of, and attitudes toward, a food.

The proposed collection of information is a controlled randomized experimental study. The study will use a 6 x 3 x 2 within-subjects design (6 front-panel health-claims/health messages x 3 diet-disease relationships x 2 prior knowledge) with participants randomly assigned to experimental conditions. 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 and not manipulated; 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 403(a)(1) and 201(n) of the act.

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, impending, or change in regulatory actions regarding these messages.

The study proposes to include the following three examples of diet-disease relationships: (1) Yogurt-calcium-osteoporosis, (2) orange juice-potassium-hypertension, and (3) olive oil-monounsaturated fatty acid-heart disease. The study includes these three relationships solely for the purpose of covering varying levels of consumer familiarity with the foods, nutrients, and risks, so the study findings may be more useful than if only one diet-disease relationship were examined. We reiterate that the choices do not in any way suggest or imply any new, impending, or change in regulatory actions regarding the use of these health claims/health messages or the scientific basis of these relationships. 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 planned universe of this experimental study is noninstitutionalized adults 18 and older who reside in households with telephones in the contiguous United States and within a 10-mile radius of each of six selected mall interview facilities in various locations. The study will use a two-phase data collection methodology. Phase 1 is a random-digit dialing telephone interview, using the GENESYS sampling system, to recruit participants and to ask about prior knowledge as well as demographic characteristics. Phase 2 is a computer-assisted, self-administered interview (CASAI) to elicit responses to experimental conditions. A contractor will administer the CASAI at mall interview facilities separately from the telephone interview and on a different date after the telephone interview of the same participants. 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. Hence, the study proposes to obtain prior knowledge in the telephone interview. To minimize unnecessary confounding by external factors, it is essential that all participants are able to look at the stimuli (i.e., labels) and stimuli are presented consistently and uniformly to all participants. The CASAI offers the advantage of consistent and uniform presentation of label images.

Target sample size of the study is 1,060 participants who complete both the telephone interview and the CASAI. Participants will be randomly assigned to the same 2 of the 18 experimental conditions in both the telephone interview and the CASAI. 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 CASAI. 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:

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

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	27	1	27	2.4	65

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	4,500	1	4,500	0.02	90
Interview	1,060	1	1,060	2.4	2,544
Total					2,699

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

These estimates are based on FDA's experience with previous consumer studies. Prior to the administration of the experiment, the agency plans to conduct a pretest of the final questionnaires to minimize potential problems in administration of the interviews. The pretest will be conducted in up to three waves, each with nine participants. The agency will use a screener to select an eligible adult in each household to participate in the study. Each pretest, as well as actual interview, is expected to last no more than a total of 2.4 hours (10 minutes for the telephone interview, 15 minutes for the CASAI, and 2 hours for traveling time to and from the CASAI location).

The anticipated sample size per condition is approximately 120. This sample size is expected to identify small to medium effects with a power of 0.8 and at the .05 significance level.

Dated: December 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0478]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information.'' This guidance document describes a means by which an implantable radiofrequency transponder system for patient identification and health information may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the implantable radiofrequency transponder system for patient identification and health information into class II (special controls). This guidance document is immediately in effect as the special control for the device, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Gail Gantt, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the implantable radiofrequency transponder system for patient identification and health information into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the Implantable Radiofrequency Transponder System for Patient Identification and Health Information device.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.