

**Memorandum**

Date July 2, 2014

From Ted Elkin, Acting Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, HFS-001

Subject Request for Emergency Clearance of the Paperwork Reduction Act Package for a Proposed Data Collection Entitled "Experimental and Eye Tracking Studies of Proposed Changes to the Nutrition Facts Label Formats"

To Andrew B. Perraut, FDA Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget

FDA's Center for Food Safety and Applied Nutrition (CFSAN) is requesting that a PRA package for a proposed data collection entitled "Experimental and Eye Tracking Studies of Proposed Changes to the Nutrition Facts Label Formats" be approved using the emergency clearance process under 5 C.F.R. § 1320.13(a)(2)(ii) because an unanticipated event has occurred.

On March 3, 2014, we issued two proposed rules to amend our labeling regulations for conventional foods and for dietary supplements to provide updated nutrition information to assist consumers in maintaining healthy dietary practices.

Subsequent to the publication of the two proposed rules we determined that consumer research would inform our final decisions on the format of the Nutrition Facts label. Many of the proposed modifications to the label are based on broad consumer research literature and design principles on labeling and communication. There is little empirical evidence on how and to what extent the proposed modifications may help consumers in understanding products' nutrition characteristics and in using the label to make dietary choices. There are several major components in the proposals that warrant close investigation, including: (1) Increasing the prominence of serving size; (2) Changing the order of "Serving Size" and "Servings Per Container"; (3) Changing the "Amount Per Serving" statement; (4) Changing the presentation of Percent DVs from the right to the left side of the label; (5) Requiring the declaration of absolute amounts of vitamins and minerals. We will also include other proposed changes that we have previously studied.

In our proposal, we also requested information on an alternative labeling format that indicates "quick facts" (e.g., amount of total carbohydrate, fat and protein) about a product's nutrient content first, and then explicitly points out nutrients to "avoid too much" of as well as nutrients to "get enough" of as a way to categorize the nutrient declarations in the Nutrition Facts label.

There is currently no empirical evidence to show how consumers may react to certain aspects of the proposed Nutrition Facts label or the alternative “quick facts” labeling. Therefore, we are proposing to conduct a new consumer experimental study to collect the necessary data and develop evidence needed for the final decisions. The data would be made available to the public for comment.

We need approval to do the study immediately, as the study will be used to support the rulemaking. We plan to complete the final rules by July 2015 and publish the final rule in March 2016 after the federal review process is complete. Before the draft is completed, we will need to review and prepare responses to public comments received as well as review any consumer research pertinent to the proposed modifications to the Nutrition Facts label and make adjustments to our proposals accordingly, if necessary.

Under normal circumstances, we would follow the process described in the Paperwork Reduction Act (PRA) and OMB’s regulations. However, we must have results of the proposed consumer research by March 2015 in order to make the results available to the public for comment, so we may incorporate the results of the research and the public comments into the drafting of the final rules by July 2015. There are less than nine months from the date of this memo to develop, conduct, analyze and report the proposed study and make results available to the public. If the normal clearance procedures are used, we would not be able to make the results of the consumer research available to the public by March 2015.

Therefore, because of the unanticipated need for more consumer evidence to inform our final decisions on the proposed modifications to the Nutrition Facts label, we are requesting permission to use the emergency clearance procedures to obtain approval of the proposed consumer study.

Due to the urgency of the need for the proposed data collection, we propose to offer a 30-day comment period if this emergency request is approved and it is deemed that publication of a Federal Register notice is necessary.

  
Ted Elkin