**Nutrition Facts Label Study**
**OMB Control No. 0910-NEW**

**SUPPORTING STATEMENT, Part A**

**Terms of Clearance:** None.

## A. Justification

1. Circumstances Making the Collection of Information Necessary

Many of the proposed modifications to the Nutrition Facts label (NFL) are based on broad 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 calories and serving size; (2) Changing the order of "Serving Size" and "Servings Per Container;" (3) Right-justifying the quantitative amounts declared in the "Serving Size" statement; (4) Changing the "Amount Per Serving" statement; (5) Removing the "Calories From Fat" declaration; (6) Changing the presentation of Percent DVs from the right to the left side of the label; (7) Requiring the declaration of "Added Sugars" on the label; (8) Requiring the declaration of absolute amounts of vitamins and minerals; and (9) Changing the Footnote section of the label.

2. Purpose and Use of the Information Collection

To help enhance FDA's understanding of consumer reactions to proposed format changes to the Nutrition Facts (NF) label by obtaining consumer judgments about a food product, based on the NF label, in terms of its individual nutritional attributes and overall healthfulness; and by the consumer's ability to use modified versions of the NF label for such tasks as calculating calories and estimating serving sizes.

*Description of Respondents:* Respondents to this information collection are 18 year-or older members of an established consumer panel and 18 year-or older consumers in one of four locations throughout the continental United States.

3. Use of Improved Information Technology and Burden Reduction

Part one of the proposed study will employ computer technology allowing participants to utilize the internet. Part two of the study will employ eye tracking study techniques to determine participant responses.

4. Efforts to Identify Duplication and Use of Similar Information

There is currently no empirical evidence to show how consumers may react to the proposed NFL or the alternative NFL. Therefore, we are proposing to conduct a new consumer experimental study to collect the necessary data and develop evidence needed for the final decisions.

5. Impact on Small Businesses or Other Small Entities

The proposed survey has no impact upon small businesses. However, FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. If this information is not collected, FDA will not have an understanding of how consumers may view label components and make inferences about the components. This knowledge would enhance the Agency's ability to develop and provide more useful labeling information to help consumers make optimize educational activity related to Nutrition Facts label information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

On March 3, 2014, FDA published in the Federal Register (79 FR 11880) a proposed rule regarding revision of the Nutrition and Supplement Facts Labels as well as other relevant rulemaking. In preparation of the timely issuance of a final rule, the agency is seeking to collect this information under the emergency review provisions of the PRA.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents. Panel members, as part of the panel procedure, participating in the online portion of this study will be entered into a prize drawing after completing the study, but will not be paid specifically for their participation in this study.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the Agency. FDA will keep the study data confidential to the extent permitted by law.

11. Justification for Sensitive Questions

This collection of information does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

Table 1.—Estimated Annual Reporting Burden

| Activity | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Avg. Burden per Response | Total Hours |
|---|---|---|---|---|---|
| Online Study | 5000 | 1 | 5000 | 15 mins. | 1250 |
| Eye Tracking | 160 | 1 | 160 | 10 mins. | 27 |
| TOTAL | | | | | 1277 |

12b. There is no annual cost burden to respondents.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The cost to the government would be $460,000, where $332,000 is attributed to conducting the study and $. $128,000 for FTEs to analyze the data.

15. Explanation for Program Changes or Adjustments

This is a new information collection request for purposes of data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval to not display the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.