

the plans and rates associated with the plans.

Information that is to be collected from state high risk pools will be collected from The National Association of State Comprehensive Health Insurance Plans (NASCHIP) at this time. Updates to this information may be submitted voluntarily. The estimated hour burden on issuers for the Plan Finder data collection in the first year is estimated as 90,400 total burden hours, or 113 hours per organization. This estimate is based on an assumed average of 450 individual plan issuers and 700 small group plan issuers per each of the four quarterly collections. It includes 30 hours per organization for training and communication.

Additionally, for each of the issuers it includes 11 hours of preparation time, one hour of login and upload time, two hours of troubleshooting and data review, and one half hour for attestation per organization per quarterly refresh. The estimated hour burden on the states is informed by the fact that they have already submitted the data once and only need to update. The overall hours estimate is 575, or 11.5 per Department of Insurance. This is premised on 2 hours of training and communication, 8 hours for data collection, and one half hour of submission. *Form Number:* CMS-10320 (OCN: 0938-1086); *Frequency:* Annually, quarterly; *Affected Public:* Business or other for-profits and States; *Number of Respondents:* 850; *Total Annual Responses:* 3,051; *Total Annual Hours:* 91,225. (For policy questions regarding this collection, contact Joe Mercer at (301) 492-4265. For all other issues, call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested parties are invited to send comments regarding the burden or any other aspect of these collections of information requirements. To ensure consideration of your comments and recommendations, they must be submitted in one of the following ways by September 13, 2012:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options"

to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS-10320/OCN 0938-1086), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 10, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-284]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection. *Title of Information Collection:* Medicaid Statistical Information System (MSIS). *Use:* The Balanced Budget Act of 1997 mandated that states report their Medicaid data via MSIS. MSIS is used by states and other jurisdictions to report fundamental statistical data on the operation of their Medicaid program. Data provided on eligibles,

beneficiaries, payments and services are vital to those studying and assessing Medicaid policies and costs. Medicaid statistical data are routinely requested by CMS, Department agencies, the Congress and their research offices, state Medicaid agencies, research organizations, social service interest groups, universities and colleges, and the health care industry. The data provides the only national level information available on enrollees, beneficiaries, and expenditures. It also provides the only national level information available on Medicaid utilization. This information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to the Congress. The data is also crucial to CMS and HHS actuarial forecasts. *Form Number:* CMS-R-284 (OCN 0938-0345). *Frequency:* Quarterly. *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 51. *Total Annual Responses:* 204. *Total Annual Hours:* 2,040. (For policy questions regarding this collection contact Kay Spence. at 410-786-1617. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by October 15, 2012:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS-R-284 (OCN 0938-0345), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 10, 2012.

Martique Jones,

*Director, Regulations Development Group,
Division B, Office of Strategic Operations and
Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2012-N-0871]

**Agency Information Collection
Activities; Proposed Collection;
Comment Request; Experimental
Studies on Consumer Responses to
Nutrient Content Claims on Fortified
Foods**

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 a study entitled “Experimental Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods.”

DATES: Submit either electronic or written comments on the collection of information by October 15, 2012.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

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 Studies on Consumer Responses to Nutrient Content Claims on Fortified Foods (OMB Control Number 0910-NEW)

I. Background

The Nutrition Labeling and Education Act gave FDA the authority to promulgate regulations which require almost all packaged foods to bear nutrition labeling. The law also allows manufacturers to provide other nutrition information on labels in the form of various types of statements, including claims, as long as such statements comply with the regulatory limits that govern the use of each type of statement. There are three types of claims that the food industry can voluntarily use on food labels: (1) Health claims, (2) nutrient content claims, and (3) structure/function claims. All claims must be truthful and not misleading (Ref. 1).

The FDA’s policy on fortification (21 CFR 104.20) establishes a set of principles that serve as a model for the rational addition of nutrients to foods. The FDA has an interest in the American public achieving and maintaining diets with optimal levels of nutritional quality, wherein healthy

diets are composed of foods from a variety of nutrient sources. The FDA does not encourage the addition of nutrients to certain food products (including sugars or snack foods such as [cookies] candies, and carbonated beverages). FDA is interested in studying whether fortification of these foods could cause consumers to believe that substituting fortified snack foods for more nutritious foods would ensure a nutritionally sound diet.

Research suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 2 through 5). The FDA, as part of its effort to promote public health, proposes to conduct two related studies to explore consumer responses to expressed and implied nutrient content claims on the labels of snack foods such as cookies, carbonated beverages, and candy. Both studies will be controlled, randomized experiments. Study 1 will use a 15-minute Web-based questionnaire to collect information from 4,000 English-speaking adult members of an online consumer panel maintained by a contractor. Study 2 will use the same questionnaire and draw a sample of 1,000 English-speaking adult participants from the same online consumer panel to test a subset of the experimental conditions employed in Study 1. Participants in Study 2 will also access the survey on the Web but will use a grocery-shopping simulation software program to participate in the study. Study 2 is expected to last 15 minutes as well.

The purpose for using both the regular Web-based application and the simulated shopping program is to be able to compare the two modes of data collection. One critique of experimental studies is that they may lack external validity—the ability to generalize the findings beyond the study setting because the study is very different from real life (Ref. 6). The grocery-shopping simulation software program may more closely mimic consumers’ real-life shopping experiences compared to the regular Web-based application and would therefore be expected to elicit survey responses similar to real-life food shopping. One study comparing simulated shopping with actual behavior concluded that consumers’ simulated purchase behaviors are highly predictive of their actual behavior (Ref. 7). If proposed Study 1 and Study 2 results are comparable, this will lend support to the external validity of online experimental study results. Researchers will endeavor to collect samples that reflect the U.S. Census on gender,