

uses an experimental design to assess consumer reactions to health claim language intended to convey both the potential health benefits and the level of scientific support for the health claim.

The comment also suggested that the information will not be useful if it is the agency's intent to alter or restrict the wording of qualified health claims because, according to the comment, consumers have the right to receive truthful information, regardless of whether they understand that information.

FDA disagrees. The agency has a responsibility to ensure that disclaimers and other qualifying language intended to prevent consumer deception are effective in serving that purpose. The study is designed to evaluate whether certain variants of the qualified health claims are more effective than others at conveying to consumers the potential health benefits and the level of scientific support for the health claim. FDA expects this study to be useful in determining language that effectively conveys this information to consumers.

The comment suggested that there might be ways to improve the quality or utility of the information collection, yet

did not offer specific recommendations to modify the study and analysis. In particular, the comment expressed concern that an Internet survey cannot be used to measure consumer confusion.

FDA responds that the experimental study that is the basis of this information collection request is an Internet-based experiment, not an Internet survey. The experimental study is intended to assess the communication effects, in a large sample of study participants, of both existing health claim language that appears on dietary supplements and conventional food products and variants of such language. The study is not intended to measure consumer confusion per se.

One comment recommended that, to help maximize the quality, utility and accuracy of the data to be collected in the study, FDA should test the qualified claim language exactly as stated in the **Federal Register** notice published March 30, 2005.

FDA agrees. The experimental study will test the qualified claim language exactly as it appears in the notice, in addition to variants of the claim language.

A comment urged FDA to take steps to ensure that using electronic data collection is reliable and verifiable for the study.

FDA is confident that the methodology is reliable and verifiable for this type of study. FDA will closely monitor the contractor that implements the experiment to ensure the validity and accuracy of the collected data.

Another comment supported FDA's efforts to understand consumer responses to food and dietary supplement labels, but expressed concern that FDA has not supplied sufficient information to evaluate whether the estimated burden of the proposed collection is accurate.

FDA believes that the estimate of burden is accurate because the estimate is based on past experience with Internet panel experiments similar in complexity and duration to the one proposed here. The study protocol will be available for public viewing when this 30-day notice is published. FDA has followed the procedures for public notice and comment about this information collection set out in the PRA (44 U.S.C. 3501-3520) and OMB regulations (5 CFR part 1320).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|--------------|
| 30 (pre-test) | 1 | 30 | .16 | 5 |
| 7,440 (experiment) | 1 | 7,440 | .16 | 1,191 |
| TOTAL | | | | 1,196 |

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

Dated: May 12, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0443]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled

“Focus Groups as Used by the Food and Drug Administration” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2006 (71 FR 9828), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0497. The approval expires on November 30, 2007. A copy of the supporting statement for

this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: May 12, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0183]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.