Additional authority for these activities appears in Section 1154(a)(8) of the Act, which requires that QIOs perform such duties and functions, assume such responsibilities, and comply with such other requirements as may be required by the Medicare statute. CMS regards survey activities as appropriate if they will directly benefit Medicare beneficiaries. In addition, Section 1154(a)(10) of the Act specifically requires that the QIOs "coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations, including other public or private review organizations as may be appropriate." CMS regards this as specific authority for QIOs to coordinate and operate a broad range of collaborative and community activities among private and public entities, as long as the predicted outcome will directly benefit the Medicare program.

The purpose of the study is to design and conduct an analysis evaluating the impact on national and regional health care processes and outcomes of the Ninth Scope of Work QIO Program. The QIO Program is national in scope and scale and affects the quality of healthcare of 43 million elderly and disabled Americans. CMS will conduct an impact and process analysis using data from multiple sources: (1) Primary data collected via in-depth interviews, focus groups, and surveys of QIOs, health care providers, and other stakeholders; (2) secondary data reported by QIOs through CMS systems; and (3) CMS administrative data. The findings will be presented in a final report as well as in other documents and reports suitable for publication in peer-review journals. This request relates to the following data collections: (1) Survey of QIO directors and theme leaders; (2) Survey of hospital QI directors and nursing home administrators; (3) focus groups with Medicare beneficiaries; and (4) in-person and telephone discussions with QIO staff, partner organizations, health care providers, and community health leaders. *Form Number:* CMS–10294 (OMB# 0938–New); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, and Medicare beneficiaries; *Number of Respondents:* 3,343; *Total Annual Responses:* 3,343; *Total Annual Hours:* 1,707. (For policy questions regarding this collection contact Robert Kambic at 410–786–1515. 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 E-mail 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *April 21, 2010.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: March 15, 2010.

Michelle Shortt,

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

[FR Doc. 2010–6237 Filed 3–19–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Assessment of the Town Hall Meetings on Underage Drinking Prevention—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP), is proposing a revision to the information collection regarding the Assessment of the Town Hall Meetings (THMs) on Underage Drinking (UAD) Prevention. The current data collection has approval under OMB #0930–0288, which expires on January 31, 2011. Revisions were made to the Town Hall Meeting Feedback Form, now being referred to as the Organizers Survey; the data collection method; and the number of respondents. Additionally, CSAP is adding a new data collection component titled the Participants Survey, which is the data collection instrument for the participants (or attendees) of the THM events.

Changes

Under the current approval, SAMHSA/CSAP distributes a brief Town Hall Meeting Feedback Form to all CBOs participating in THM events. This paper-and-pencil based form includes 14 items about the THM event, among which—

- Where, when, and who conducted the meeting;
- Number of attendees;
- Format of the meeting;
- Participants in the presentations;
- Actions planned;
- Media coverage;
- Composition of the audience;
- Responses of the attendees;
- Materials provided;
- Indications of increased awareness; and
- Indications of increased involvement.

Under this revision, SAMHSA/CSAP will provide organizers of THM events with password-protected login information to access the Organizers Survey via the Internet. The Organizers Survey includes 36 items about the THM event. Listed below is a summary of the revisions that were made—

Reworded topics/questions	New topics/questions
• Date of THM event. • Location of THM event. • Organization(s) coordinating the THM event. • Format/Features of the THM event. • Promotion of the THM event. • Participants in the THM event presentations. • Major actions planned as a result of the THM event. • Overall satisfaction with the THM event. • Sharing of any other important features of reactions to the THM event. • Number/Composition of THM attendees.	• Indication of whether a THM event was not held and reason why the event was not held. • Venue in which THM event was held. • Characterization of the THM event location. • Duration of the THM event (in hours and minutes). • Youth involvement in the THM event. • Topic of THM event, if other than underage drinking. • Demographics of the participants (age, race, gender). • Language of the THM event. • Use of materials from the *http://www.stopalcoholabuse.gov* Web site. • Participation in THM-related Webinars. • Viewing of online training and requests for technical assistance (TA). • Satisfaction with training and/or TA received. • Improved capacity to provide effective UAD services due to training and/or TA received. • Implementation of training and/or TA recommendations. • Indication of whether data were collected about the THM event and willingness to share those data with CSAP.
Deleted topics/questions	
• Description of meeting. • Organization affiliation. • Overall response of THM event attendees. • Use of materials from the THM resource kit. • Indications of increased awareness. • Indications of increased involvement.	

New Data Collection Component

SAMHSA/CSAP will provide organizers of THM events with a unique URL to make available to participants of their THM event. This unique URL provides access to the Participants Survey. The Participants Survey includes 17 items about the THM event, among which—

- When and where the THM event was held;
- Estimation of the number of attendees at the THM event;
- Perception of increased awareness;
- Indication of reach of the underage drinking prevention messages from the THM event;
- Perception of increased involvement;
- Indication of the most important underage drinking issues facing the community;
- Perception of how well the THM event addressed those issues;
- Appropriateness of the THM event in terms of length and duration;
- Overall assessment of the THM event; and
- Demographics of the participants.

The Organizers Survey will be completed by an estimated 3,400 THM event organizers and will require only one response per respondent. It will take an average of 30 minutes (0.500 hours) to review the instructions and complete the survey. This burden estimate is based on comments from several potential respondents who reviewed the survey and provided comments on how long it would take them to complete it.

The Participants Survey will be completed by an estimated nine participants per THM event and will require only one response per respondent. The estimated number of participant respondents is based on 21 percent of the average of the sum of adult (66,519) and youth (53,554) participants, as reported on the 2008 THM events feedback forms (1,492 forms reported adults as participants and 1,316 forms reported youth as participants) [(120,073/2,808 = 42.76) x 0.21 = 8.9798]. It will take an average of 10 minutes (0.167 hours) to review the instructions and complete the survey. This burden estimate is based on comments from several potential respondents who reviewed the survey and provided comments on how long it would take them to complete it.

Form name	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Organizers Survey	3,400	1	0.500	1,700.00
Participants Survey	30,600 (9 responses per THM event [3,400]).	1	0.167	5,110.20
Total	34,000			6,810.20

SAMHSA/CSAP intends to support THM events every other year. The information collected will be used by SAMHSA/CSAP to help plan for these biennial events, to provide technical assistance and training to organizations that sponsor the events, and to comply with the reporting requirements of the Government Performance Results Act of 1993. The information collected will also provide a descriptive picture of the nationwide initiative, and it will indicate how the THM events were received by the community and factors that may be associated with well-received events.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail a copy to *summer.king@samhsa.hhs.gov.*

Written comments should be received within 60 days of this notice.

Dated: *March 15, 2010.*

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–6192 Filed 3–19–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0117]

Agency Information Collection Activities; Proposed Collection: Comment Request: Guidance for Industry Entitled Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

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 the information collection associated with the guidance "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims," which is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension.

DATES: Submit written or electronic comments on the collection of information by May 21, 2010.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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 that 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.

Guidance for Industry entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims" 21 CFR 201.56 and 201.57—(OMB Control Number 0910—New)

This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. The guidance encourages applicants to submit labeling supplements containing the new language.

In the **Federal Register** of March 13, 2008 (73 FR 13546), FDA published the draft guidance entitled "Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims." The draft guidance contained no information collection subject to OMB review under the PRA. The final guidance, however, contains two new provisions that are subject to OMB review and approval under the PRA, and one new provision that would be exempt from OMB review. Under the PRA, FDA must first obtain OMB approval for this information collection before we may issue the final guidance.

(1) Section IV.C of the guidance requests that the CLINICAL STUDIES section of the Full Prescribing Information of the labeling should include a summary of placebo- or active-controlled trials showing evidence of the specific drug's effectiveness in lowering blood pressure. If trials demonstrating cardiovascular outcome benefits exist, those trials also should be summarized in this section. Table 1 in section V of the guidance contains the specific drugs for which the FDA has concluded that such trials exist. If there are no cardiovascular outcome data to cite, one of the following two paragraphs should appear:

"There are no trials of [DRUGNAME] or members of the [name of pharmacologic class] pharmacologic class demonstrating reductions in cardiovascular risk in patients with hypertension," or "There are no trials of [DRUGNAME] demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits."

In the latter case, the applicant's submission generally should refer to table 1 in section V of the guidance. If the applicant believes that table 1 is incomplete, it should submit the clinical evidence for the additional information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. FDA estimates that no more than 1 submission to the docket will be made annually from 1 company, and that each submission will take approximately 10 hours to prepare and submit. Concerning the