collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 17, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–3958 Filed 2–25–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Understanding Patients' Knowledge and Use of Acetaminophen.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by April 27, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

''Understanding Patients' Knowledge and Use of Acetaminophen''

This proposed data collection is a qualitative study to preliminarily identify issues that relate to the misuse and overdosing of over-the-counter (OTC) acetaminophen. Toxicity from acetaminophen has been on the rise in the past 3 decades, and is now the most common cause of acute liver failure in the U.S., surpassing viral hepatitis. This data collection has two aims. Aim 1 is to qualitatively explore knowledge, attitudes, beliefs, and practices regarding adult and adolescent self-administration of OTC acetaminophen, and parental administration of OTC acetaminophen to children. To meet Aim 1, focus groups will be conducted with adults and semi-structured interviews will be conducted with adolescents. Aim 2 is to qualitatively explore experiences and practices of key professional informants, including physicians and pharmacists, with respect to communicating information on the administration and risks of OTC acetaminophen to consumers and patients. Semi-structured interviews will be conducted with target key informants. The results of this qualitative study will provide an understanding of the relevant issues and will be used to develop a comprehensive survey. A second OMB clearance package will be developed once the questionnaire for the survey is available.

This project is being funded by AHRQ pursuant to a cooperative agreement with the University of Pennsylvania (Award 1 U18HS017991) as part of the Centers for Education and Research on Therapeutics (CERTs) program. The CERTs program is a national initiative, administered by AHRQ in consultation with the Food and Drug Administration, to increase awareness of the benefits and risks of new, existing, or combined uses of therapeutics through education and research. *See* 42 U.S.C. 299b–1(b).

Method of Collection

Aim 1—Focus groups and individual interviews

Four focus groups will be conducted with parents of young children to examine administration of acetaminophen to children. Four focus groups will also be conducted with adults to identify the issues, barriers, and psychosocial factors surrounding how, when, and why OTC acetaminophen is used. Focus groups will each have 6 to 8 participants. Semi-structured interviews will be conducted with adolescents to examine self-administration of acetaminophen among this group.

Content areas to be explored are: a. Knowledge about acetaminophen: Brands, terms, combinations, dosage, administration, indications; b. beliefs about benefits and risks, including thresholds for toxicity and death; c. patterns and frequency of use; d. sources of information (*e.g.*, physicians, pharmacists, media); e. related experiences in peers (*e.g.*, advice, reports of toxicity); and f. views about labeling, packaging and legislation (*e.g.*, restrictions in sales).

Aim 2—Semi-structured interviews with physicians and pharmacists

Twenty primary care physicians and 20 pharmacists will be interviewed. Primary care physicians will be recruited through a primary care research network of physicians from both private and public clinics. Pharmacists will be recruited at pharmacy facilities from hospitals and clinics. Interviews will be conducted over the phone or in person, according to the participant's preference, and will last approximately 20 minutes. All interviews will be audio-taped and transcribed. Participants will be asked about the following: a. Frequency and patterns of interaction with consumers and patients with respect to acetaminophen; b. types of information provided to consumers; c. availability of education materials; and d. views about labeling, packaging and legislation.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this project. The screening form will be completed by all participants and is expected to take approximately 3 minutes to complete. Focus groups will include 2 populations: Parents of children 8 years of age and adults, and will last about 1½ hours. Semi-structured interviews will be conducted with 20 adolescents, 20 primary care physicians, and 20 pharmacists and will last 20 to 30 minutes. The self-administered questionnaire will be completed by the focus group participants and the adolescent participants of the semi-structured interviews, and will take about 6 minutes to complete. The total burden for all participants is estimated to be 134 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondent's time to participate in the project. The total cost is estimated to be $2,001.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Screening form	124	1	3/60	6
Self-administered questionnaire	84	1	6/60	8
Focus group with parents of children <8 years of age (4 groups of 8 participants)	32	1	1.5	48
Focus group with adults (4 groups of 8 participants)	32	1	1.5	48
Semi-structured interviews with adolescents (13 to 20 years of age)	20	1	30/60	10
Semi-structured interviews with primary care physicians	20	1	20/60	7
Semi-structured interviews with pharmacists	20	1	20/60	7
Total	332			134

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening form	124	6	$10.30	$62
Self-administered questionnaire	84	8	10.30	82
Focus groups with parents of children <8 years of age (4 groups of 8 participants)	32	48	10.30	494
Focus groups with adults (4 groups of 8 participants)	32	48	10.30	494
Semi-structured interviews with adolescents (13 to 20 years of age)	20	10	10.30	103
Semi-structured interviews with primary care physicians	20	7	61.10	428
Semi-structured interviews with pharmacists	20	7	48.22	338
Total	332	134		2,001

*Patient average hourly wage based on the average per capita income of $21,435 (computed into an hourly wage rate of $10.30) in Harris County, Texas where the study will take place. Provider hourly wage based on the following estimates from National Compensation Survey: Occupational wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics: Primary care physician = $61.10/hour; pharmacist = $48.22/hour.

Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated cost to the Federal Government for this six month project.

The total cost is $164,440. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost
Project Development	$13,250
Data Collection Activities	61,699
Data Processing and Analysis	14,080
Publication of Results	750
Project Management	17,000
Overhead	57,661
Total	164,440

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 17, 2009.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0631]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 30, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,