Dated: July 24, 2003.

Laura Y. Martin,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–03–101]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Agency for Toxic Substances and Disease Registry (ATSDR) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404)498–1210.

Comments are invited on: (a) Whether the proposed collection of information is 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. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Evaluation of Customer Satisfaction of the Agency for Toxic Substances and Disease Registry (ATSDR) Web Site (OMB No. 0923–0028)—Reinstatement—ATSDR proposes to conduct customer satisfaction research for its Internet site. Information on the site focuses on prevention of exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances from waste sites, unplanned releases, and other sources of pollution present in the environment. The site is designed to serve the general public, persons at risk for exposure to hazardous substances, and health professionals.

Approval for a similar Customer Satisfaction Survey was requested in 2002 jointly with the Centers for Disease Control and Prevention (OMB No. 0920–0449, Expiration Date 09/30/2003). The new survey is solely for ATSDR and is significantly shorter and would require less time to complete.

This research will ensure that targeted audiences find the information easy to access, clear, informative, and useful. Specifically, the research will examine whether the information is presented in an appropriate technological format and whether it meets the needs, wants, and preferences of visitors or ''customers'' to the Web site. Results from the previous survey were utilized to redesign the ATSDR Web site—making improvements to architecture, links, organization, and content. Results from the new survey will assist ATSDR in making more improvements to the Web Site in order to better serve its customers/visitors. There will be no costs to respondents.

Respondents	Number of respondents	Number of responses/respondent	Average Burden per response (in hrs.)	Total Burden (in hrs.)
Visitors to ATSDR Web site	1,000	1	5/60	83

Dated: July 28, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–19579 Filed 7–31–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–102]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404)498–1210.

Comments are invited on: (a) Whether the proposed collection of information is 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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Data Collection and Analysis to Determine the Reliability and Validity of Current and Proposed Oral Health Questions, Behavioral Risk Factor Surveillance System—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, proposes to support data collection and analysis to determine the reliability and validity of current and proposed Oral Health questions for the Behavioral Risk Factor Surveillance System (BRFSS). At the request of the Association of State and Territorial Dental Directors (ASTDD), the Division of Oral Health (DOH) provided technical assistance in standardization of questions to monitor the oral health of adults. Three questions appeared on the BRFSS core in 1999, and were included again in 2002; They permit state dental programs to track progress toward Healthy People

(HP) objectives for adults (HP 2010: 21–3, 21–4, 21–10), to monitor reported use of a key preventive service for adults (teeth cleaning), and to examine the relationship of oral health indicators to general health status, conditions, and behaviors.

As more state dental programs consider the oral health of adults, states have requested that a bank of additional standardized questions be created to monitor other oral health indicators. CDC/DOH has been reluctant to provide additional technical assistance, without firm data on the reliability and validity of questions. Because all BRFSS questions require self-report by respondents about their own oral health status or behaviors, recall bias and errors in perception exist. To accomplish estimates of response error, answers to existing and proposed BRFSS questions (limit = 10 content questions, plus 7 demographic questions) must be compared to the ''True'' situation of that individual, *i.e.*, that is found in patient charts or other clinical records.

The proposed data collection and analysis will be conducted through the Alliance of Community Health Plans by research foundations affiliated with two dental plans, Kaiser Permanente Northwest, Portland, OR and Health Partners, Minneapolis, MN. The proposed telephone survey, similar to BRFSS, of a convenience sample of 400 dental plan members (200 from each respective HMO) would occur only once. Neither published studies nor informal discussions with dental researchers regarding work in progress uncovered any information that would eliminate the need for this data collection. All work on this project, including linkages between health plan records and responses to the BRFSS questions, will be conducted at the research foundations associated with the respective health plans. CDC will receive only a report on the validity of the questions, and will not have access to the database constructed for the contract.

Study findings will allow CDC to respond to state requests for inclusion of additional standardized questions in an optional oral health module for BRFSS and ensure that any such questions are reliable, valid, and useful for state program planning and evaluation. There is no cost to respondents.

Health plan respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
Kaiser Northwest	200	1	15/60	50
Health Partners	200	1	15/60	50
Total	.....	.....	.....	100

Dated: July 28, 2002.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–19580 Filed 7–31–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0036]

Determination of Regulatory Review Period for Purposes of Patent Extension; SPECTRACEF

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPECTRACEF and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SPECTRACEF (cefditoren pivoxil). SPECTRACEF is indicated for treatment of acute exacerbation of chronic bronchitis, pharyngitis/tonsillitis, and uncomplicated skin and skin structure infections. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SPECTRACEF (U.S. Patent No. 4,839,350) from Meiji Seika Kaisha, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 4, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SPECTRACEF represented the first permitted commercial marketing or use of the