Assessment of Fall Prevention Programs. This approval expires on 7/31/10. At this time we are requesting a two year extension to collect data. NCIPC seeks to examine cost of implementing each of the three AoA-funded fall prevention programs for older adults (Stepping On, Moving for Better Balance and Matter of Balance) and to assess the maintenance of fall prevention behaviors among participants six months after completing the Matter of Balance program.

To assess the maintenance of fall prevention behaviors, CDC's contractor, Booz Allen Hamilton, will conduct telephone interviews of 300 Matter of Balance program participants six months after they have completed the program. The interview will assess their knowledge and self-efficacy related to falls as taught in the course, their activity and exercise levels, and their reported falls both before and after the program. The results of the follow-up assessment will determine the extent to which preventive behaviors learned during the Matter of Balance program are maintained and can continue to reduce fall risk.

The cost assessment will calculate the lifecycle cost of the Stepping On, Moving for Better Balance, and Matter of Balance programs. The cost analysis will include calculating the investment costs required to implement each program, as well as the ongoing operational costs associated with each program. These costs will be allocated over a defined period of time, depending on the average or standard amount of time these programs continue to operate (standard lifecycle analysis ranges from five to 10 years). The data obtained from the lifecycle cost calculation will allow us to compare program costs and to identify specific cost drivers, cost risks, and unique financial attributes of each program.

Local program coordinators for the 200 sites in each of the AoA-funded states will collect the cost data using lifecycle cost spreadsheets that will be returned to CDC's contractor for analysis. Booz Allen Hamilton has been contracted by CDC to conduct the data collection and analysis.

The results of these studies will support the replication and dissemination of these fall prevention programs and enable them to reach more older adults. States require data on impact and cost in order to obtain sustainable and supplemental funding to maintain programs after funding from AoA ends.

There are no costs to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses	Average burden per response (in hours)	Total burden (in hours)
Program Coordinators	Cost Assessment	200	1	2	400
Program Participants	Impact Survey	300	1	1	300
Total					700

Dated: August 28, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–21377 Filed 9–3–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NCCAM Customer Service Data Collection

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Complementary and Alternative Medicine (NCCAM), the National Institutes of Health (NIH), will submit to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. A notice of this proposed information collection was previously published in the **Federal Register** on June 26, 2009 (Volume 74, Number 122, page 30577). To date, no public comments have been received. The purpose of this notice is to announce a final 30 days for public comment. NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NCCAM Customer Service Data Collection.

Type of Information Collection Request: Revision.

Need and Use of Information Collection: NCCAM provides the public, patients, families, health care providers, complementary and alternative medicine (CAM) practitioners, and others with the latest scientifically based information on CAM and information about NCCAM's programs through a variety of channels, including its toll-free telephone information service. NCCAM wishes to continue to measure customer satisfaction with NCCAM telephone interactions and to assess which audiences are being reached through these channels. This effort involves a telephone survey consisting of 10 questions, which 25 percent of all callers are asked to answer, for an annual total of approximately 983 respondents. NCCAM uses the data collected from the survey to help program staff measure the impact of their communication efforts, tailor services to the public and health care providers, measure service use among special populations, and assess the most effective media and messages to reach these audiences.

Frequency of Response: Once.

Affected Public: Individuals and households.

Type of Respondents: Patients, spouses/family/friends of patients, health care providers, physicians, CAM practitioners, or other individuals contacting the NCCAM Clearinghouse.

The annual reporting burden is as follows:

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Telephone survey				
Individuals or households	919	1	0.075	69
Physicians	44	1	0.075	3
CAM/health practitioners	20	1	0.075	1

The annualized cost to respondents is estimated at $1,479 for the telephone survey. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 31 Center Drive, Room 2B–11, Bethesda, MD 20892–2182; or fax your request to 301–402–4741; or e-mail *thomsenc@mail.nih.gov*. Ms. Thomsen can be contacted by telephone at 301–451–8876.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 27, 2009.

Christy Thomsen,

Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.

[FR Doc. E9–21479 Filed 9–3–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0266]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DORIBAX 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 which 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 DORIBAX (doripenem monohydrate). DORIBAX is indicated in the treatment of the following infections caused by designated susceptible bacteria: complicated intra-abdominal infections, and complicated urinary tract infections, including pyelonephritis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DORIBAX (U.S. Patent No. 5,317,016) from Shionogi Seiyaku Kabushiki Kaisha, 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 18, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the