burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Medical Devices: Humanitarian Use Devices—21 CFR Part 814—Subpart H (OMB Control Number 0910–0332)—Extension**

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814, subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnosis a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnosis the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grants marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making those determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of respondents: Businesses or others for-profit.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 814.102 | 20 | 1 | 20 | 40 | 800 |
| 814.104 | 15 | 1 | 15 | 320 | 4,800 |
| 814.106 | 15 | 4 | 60 | 50 | 3,000 |
| 814.108 | 12 | 1 | 12 | 80 | 960 |
| 814.116(e)(3) | 1 | 1 | 1 | 1 | 1 |
| 814.124(a) | 5 | 1 | 5 | 1 | 5 |
| 814.124(b) | 1 | 1 | 1 | 2 | 2 |
| 814.126(b)(1) | 15 | 1 | 15 | 120 | 1,800 |
| Total | | | | | 11,368 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 814.126(b)(2) | 15 | 1 | 15 | 2 | 30 |
| Total | | | | | 30 |

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

Generally, the information requested from the respondents represents an accounting of information already in the possession of the applicant.

In the final rule for HUDs, published in the **Federal Register** of June 26, 1996 (61 FR 33232), FDA based its estimates on comments received to the proposed rule, industry contact, and internal FDA benchmark factors (such as the number of premarket approval applications (PMAs) processed). The numbers generated in the current estimate as shown in tables 1 and 2 of this document and described in the following paragraphs are based upon those prior estimates. This is still a relatively new program, and the data acquired from the past several years has remained fairly stable and consistent.

Dated: July 24, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–19243 Filed 7–30–02; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

*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 the use of automated collection techniques or other forms of information technology.

**Proposed Project: National Health Service Corps (NHSC) Waiver Request Worksheets (OMB No. 0915–0234)—Revision**

The National Health Service Corps (NHSC) of the HRSA's Bureau of Health Professions (BHPr), is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care.

The NHSC Site Bill is sent to all sites where NHSC members have been assigned for all or part of the calendar year. The sites are billed for the full amount of the calculated costs associated with the assignee(s). The Public Health Service Act, Section 334 contains provisions which permit a waiver of the reimbursement requirement for entities which are assigned Corps members. The Waiver Request Worksheets are used by the NHSC to collect the necessary information from sites which are requesting a waiver to determine if such a waiver is justified.

Estimates of annualized reporting burden are as follows:

| Type of report | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Billing Form | 1200 | 1 | 1200 | .25 | 300 |
| Budget Form | 1200 | 1 | 1200 | .75 | 900 |
| Total | 1200 | 1 | 2400 | 1.00 | 1200 |

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 25, 2002.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 02–19302 Filed 7–30–02; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institues of Health

**[CHIS–CAM]**

### Submission for OMB Review; Comment Request California Health Interview Survey—Complementary and Alternative Medicine [CHIS–CAM]

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 22, 2002, pages 2892–2893 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health 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:* California Health Interview Survey—Complementary and Alternative Medicine (CHIS–CAM). *Type of Information Collection Request:* New. *Need and Use of Information Collection.* The NCI has sponsored a Cancer Control Topical Module (CCTM) to the California Health Interview Survey (CHIS), administered in 2001. The CHIS is a telephone survey designed to provide population-based, standardized health-related data. Initiated by the USLA Center for Health Policy Research, California Department of Health Services, and the Public Health Institute, the survey was funded by a number of public and private sources.

The 2001 CHIS CCTM was similar in content to the 2000 National Health Interview Survey (NHIS) CCTM and was administered to one sample adult in more than 54,000 households. NCI anticipates comparing the CHIS and NHIS data in order to conduct comparative and pooled analyses that will enable better estimates of health-related behaviors and cancer risk factors for smaller racial/ethnic minority populations.

The CHIS–CAM is a cross-sectional telephone survey nested in the CHIS study population of all adult respondents who agreed to be re-contacted. Complementary and Alternative Medicine (CAM) is a rapidly growing component of prevention and treatment of chronic illness in the United States. Yet the study of cancer has been largely excluded from the existing population-based surveys on CAM due to sample size restrictions, and little reliable information exists on how CAM utilization varies among different ethnic groups and among those with chronic illnesses.

The CHIS–CAM survey will be administered to approximately 2,000 cancer survivors and 6,000 non-cancer adults. It will enable NCI to collect extensive information on CAM, cancer and other chronic illnesses, and link it with the breadth of basic data already collected from the large, racially and ethnically diverse sample of CHIS respondents.

Comprehensive and detailed collection of information on CAM will enable NCI to increase its understanding of how, why, and to what effect CAM is used. The CHIS–CAM survey data will allow NCI to compare individuals who report various types of cancer and other chronic conditions and to determine: (1) The major categories of CAM procedures being used, as well as the specific therapies targeted toward cancer prevention and treatment, (2) how various subgroups in the population (defined by race/ethnicity, gender, age, health status, etc.) compare with regards to CAM procedures being used; (3) to what extent persons with cancer used specific types of CAM before or after diagnoses with cancer, and whether cancer patients used CAM in place of, or in addition to, conventional medical care; (4) whether systematic CAM treatments for cancer might lead to harm or interact with conventional treatments for cancer; and (5) what expenditures people are paying out-of-pocket for CAM procedures. *Frequency of Response.* One-time. *Affected public:* Individuals. *Type of Respondents:* U.S. adults. The annual reporting burden is as follows: