

support of each technical section are covered by an existing paperwork clearance under OMB control number 0910-0032. FDA is seeking new paperwork clearance for the cover letter, table of contents, and summary that should accompany each submission. The cover letter identifying the submission as a "phased submission" should: (1) Describe briefly the purpose of the submission and the information contained in it, (2) reference or attach any pertinent documentation regarding previous agreements or understandings between the sponsor and CVM, (3) identify persons CVM may contact regarding any specifics of the

submission, and (4) convey any other information the sponsor considers important or necessary to facilitate the review of the submission. There are potentially eight technical sections: Chemistry, manufacturing and controls; effectiveness; target animal safety; human food safety; environmental impact; labeling; freedom of information (FOI) summary; and, all other information.

After a sponsor has received technical section complete letters for each technical section containing information required for the approval of the new animal drug, the sponsor may file an administrative NADA. The

administrative NADA should include a cover letter identifying the submission as an "Administrative NADA," a signed FDA Form 356V, a table of contents, summary, copies of the technical section complete letters for each required technical section, complete facsimile labeling, and the FOI summary.

The cover letters that should be provided with each submission and with the administrative NADA and the copies of technical section complete letters represent new paperwork.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Administrative NADA applications	190	.24	47	4	188
Phased submissions	190	1.31	250	2	500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA averaged the number of administrative NADA applications and phased submissions for the past 2 years. Hours per response took into account that cover letters submitted summarized information contained in the submission and did not require any new information.

**IV. Comments**

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this draft guidance document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Submit written comments concerning the information collection requirements to the Dockets Management Branch. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on the Internet site, select 02D-0449 "The Administrative New Animal Drug

Application Process" and follow the directions. A copy of this document may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: October 28, 2002.  
**Margaret M. Dotzel**,  
*Associate Commissioner for Policy.*  
 [FR Doc. 02-28257 Filed 11-5-02; 8:45 am]  
**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Notice of Senior Executive Service Performance Review Board Membership**

The Health Resources and Services Administration (HRSA) announces the appointment of members to the HRSA Senior Executive Service (SES) Performance Review Board (PRB). This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4) of the Civil Service Reform Act of 1978, which requires members of performance review boards to be published in the **Federal Register**.

The function of the PRB is to ensure consistency, stability and objectivity in SES performance appraisals, and to make recommendations to the Administrator, HRSA, relating to the performance of senior executives in the Agency.

The following persons will serve on the HRSA SES Performance Review Board:

- Dennis P. Williams, Neil Sampson, Stephen R. Smith, Katherine M. Marconi, Mary J. Horner, Douglas Morgan, Patricia L. Mackey, Catherine A. Flickinger, Merle G. McPherson, William D. Hobson, Marcia K. Brand, Peter C. van Dyck, J. Henry Montes, James Macrae, Jon L. Nelson, Denise H. Geolot, Samuel Shekar, Kerry Nessler, Deborah Parham.

For further information about the HRSA Performance Review Board, contact Ms. Wendy Ponton, HRSA Office of Human Resources and Development, 5600 Fishers Lane, Room 14A43, Rockville, Maryland 20857.

Dated: October 30, 2002.  
**Elizabeth M. Duke**,  
*Administrator.*  
 [FR Doc. 02-28153 Filed 11-5-02; 8:45 am]  
**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Patterns and Consequences of Alcohol Use in Non-Reservation Indians**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the opportunity for public

comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) will publish periodic summaries of proposed projects submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Patterns and Consequences of Alcohol Use in Non-Reservation Indians. *Type of Information Collection Request:* New. *Form Number:* No form number has been assigned because this is a new survey. *Need and Use of Information Collection:* This survey will be done in preparation for a broader study to follow. The broader study will examine the enhanced vulnerability of some American Indian people to alcohol abuse, alcoholism and adverse consequences of drinking. Most of the existing research has been restricted to reservation-residing tribes. This study will examine non-reservation individuals and thus be better representative of the majority of American Indians. Second, the samples in existing studies are predominantly male. This fact may reflect the disproportionate occurrence of substance abuse disorders in American Indian males. However, it may also reflect a sampling bias. Third, sources of the reported heterogeneity among tribes in drinking practices and outcomes are seldom examined systematically. Therefore, there is a need for the systematic study of male and female non-reservation residing American Indians and their patterns/consequences of alcohol use. The proposed telephone survey is a feasibility study to ascertain: (a) The effectiveness of this research modality in reaching non-reservation American Indians in Oklahoma (as many as 25% of non-reservation American Indians do not have access to a private phone) (b) the appropriateness of the length of the instrument and (c) the clarity and specificity of the questions. Respondents will be asked twenty-eight questions about community perceptions of substance use, service availability, familial substance use, general health concerns, and current problems related to these issues. Respondents will be American Indian individuals over the age of 21 who meet initial criteria and who are reached by random telephone sampling within Oklahoma. Information gained and strategies tested in the telephone survey will also inform methodologies and survey protocols for subsequent in person and mail surveys of American Indians that will investigate American Indian health concerns. The NIAAA is

the federal agency with primary responsibility for supporting and conducting biomedical and behavioral research on the causes, consequences, treatment, and prevention of alcoholism and alcohol-related problems. One of the Institute's goals is to examine and address alcohol consumption, its biomedical sequelae and the prevention and treatment of alcohol dependence and alcohol related pathology in specific American Indian populations. *Frequency of Response:* Once per respondent. *Affected Public:* Individuals. *Type of Respondents:* American Indian adults over 21 years of age. The reporting burden is as follows: *Estimated Number of Respondents:* 50. *Estimated Number of Responses per Respondent:* One response per respondent. *Average Burden Hours per Response:* One-third hour per individual. *Estimated Total Annual Burden Hours Requested:* 16.7 hours. There are no costs to respondents. There are no capital costs, operating costs or maintenance costs to report.

*Request for Comments:* Written comments and suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Carmen M. Richardson, NIH/NIAAA/OCR, 6000 Executive Boulevard, Suite 302, MSC 7003, Bethesda, MD 20892-7003, or e-mail your request to: [crichard@mail.nih.gov](mailto:crichard@mail.nih.gov). Ms. Richardson can be contacted by telephone at 301-443-1285.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: October 29, 2002.

**Stephen Long,**

*Executive Officer, NIAAA.*

[FR Doc. 02-28110 Filed 11-5-02; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request; Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture—Influence of Corn Farming on the Immune System Sub-Study**

**SUMMARY:** 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 National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture—Influence of Corn Farming on the Immune System Sub-study. *Type of Information Collection Request:* Revision of a currently approved collection (0925-0406, expiration 11/30/03). *Need and Use of Information Collection:* The Agricultural Health Study (AHS) is an ongoing prospective cohort study of 89,658 farmers, their spouses, and commercial applicators of pesticides from Iowa and North Carolina. The proposed collection of additional information is intended to assess the effects of corn farming activities and exposures during the farming season on the immune system. The collection is intended to determine whether there are immune changes or altered immune function occurring in corn farmers and whether such perturbations are associated with specific farming exposures or activities, such as exposure to certain pesticides during planting or grain dusts during harvesting. The characterization of any changes in immune function occurring in corn farmers may contribute to understanding of the etiology of immune-related diseases that have increased incidence among farmers, including non-Hodgkin's lymphoma and other immune-related cancers. In addition, identification of specific exposures associated with immune