

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510.305	1,070	1	1,070	0.03	32.10

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

The estimated annual reporting burden on industry is 36.6 hours, as shown in table 1 of this document. Industry estimates it takes about 0.25 hours to submit the application. We estimate 132 original and supplemental applications and voluntary revocations for a total of 33 hours (132 submissions x 0.25 hours). An additional 3.6 hours are added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 36 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated .03 hours for each of approximately 1,070 licensees. Thus, the total burden for recordkeeping requirements is 32.10 hours (1,070 licensees x 0.03 hours).

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Center for Natural Products Research, University of Mississippi; Single Source Cooperative Agreement; Catalog of Federal Domestic Assistance Number 93.103; Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source competing continuation application for the award of a cooperative agreement in fiscal year (FY 2006) to the University of Mississippi (UM) to support the National Center for Natural Products Research (NCNPR), which is located on UM's Campus at Oxford, MS, for up to \$2.3 million for FY06 (direct plus indirect costs combined), the total amount being subject to annual budget appropriations. The funds will provide additional support to the UM's NCNPR for the purpose of promoting more

efficient development and dissemination of natural products research and science and will complement the diverse activities of both the public and private sectors that may become collaborators.

Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No.93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

II. Eligibility Information

FDA believes that there is compelling evidence that UM is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. UM is a comprehensive research institution with numerous academic programs relevant to FDA's mission and the resources to support the Center for Food Safety and Nutrition's (CFSAN's) areas of interest.

NCNPR, which opened in July 1995, is a division of the Research Institute of Pharmaceutical Sciences of UM's School of Pharmacy. NCNPR was created to bring together an alliance of academia, government, and industry to integrate research, development, and commercialization of potentially useful natural products.

The goal of NCNPR in botanical dietary supplements is to enable safe, effective, and proper use of high quality botanical products by informed professionals and consumers. NCNPR conducts basic and applied multidisciplinary research to discover and develop natural products for use as dietary supplements. NCNPR also maintains a repository of several thousand natural product extracts that are available for screening by collaborators working in other areas.

NCNPR has substantial expertise to carry forward specific discoveries, products, and technologies. Most of the projects to develop promising high priority products or technology are conducted in collaboration with industrial partners or through externally

funded grants and contract. NCNPR is staffed with a highly synergistic mix of full-time research faculty and support staff and employs a number of undergraduate and graduate students and postdoctoral scientists. Together, the faculty, scientists, staff, students, and external collaborators, provide the human resources required to accomplish the research and development goals of NCNPR.

Collaboration between the public and private sector is an efficient means for both FDA and the University to remain current with scientific and technical accomplishments from a natural products research perspective. Harmonizing research activities is but one example of the need for and use of this natural products research knowledge and expertise. The partnership between FDA and UM will provide both the technical and educational expertise necessary for effective mechanisms that will facilitate the movement of new technology and provide direct usefulness to FDA's scientific and enforcement initiatives.

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, applicants should go to <http://www.grants.gov/RequestaDUNS> or call 1-866-705-5711. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

III. Application and Submission

To comply with the President's Management Agenda, HHS is participating as a partner in the new government-wide *Grants.gov* Web site. Users of *Grants.gov* will be able to download a copy of the application package, complete it offline, and then upload and submit the application via the *Grants.gov* Web site. We encourage applicant submission through *Grants.gov*. If submitted other than electronically, please contact Gladys M. Bohler for guidance (see contact

information in the paragraph that follows).

For further information contact Gladys M. Bohler, Grants Management Specialist, Division of Contracts and Grants Management (HFA-500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7168, e-mail: Gladys.Melendez_Bohler@fda.hhs.gov. A copy of the complete Request for Applications (RFA) can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at <http://www.foodsafety.gov/nfsg/fsggrant.html> (FDA has verified the Web site and its address but we are not responsible for changes to the Web site or its address after this document publishes in the **Federal Register**.)

IV. Submission Dates and Times

The application receipt date is September 25, 2006. The application will be accepted from 8 a.m. to 4:30 p.m., Monday through Friday until the established receipt date. The application will be considered received on time if hand delivered to the address noted previously (see section III of this document) before the established receipt date, or sent or mailed by the receipt date as shown by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier. Private metered postmarks shall not be acceptable as proof of timely mailing. If not received on time the application will not be considered for review and will be returned to the applicant. (Applicants should note the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office). Please do not send applications to the Center for Scientific Research (CSR) at the National Institutes of Health (NIH). Any application sent to NIH/CSR that is forwarded to the FDA Grants Management Office and not received in time for orderly processing will be judged non-responsive and returned to the applicant. Currently, FDA is unable to receive applications electronically. The applicant is advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH for its applications.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Division of Nursing Services, Public Health Nursing

Announcement Type: New competitive

Funding Announcement Number: HHS-2006-IHS-NU-0001

Catalog of Federal Domestic Assistance Number(s): 93.933

Key Dates: Application deadline Date: September 15, 2006.

Review Date: September 20-22, 2006.

Award Announcement Date: September 25, 2006.

Earliest Anticipated Start Date: September 29, 2006.

1. Funding Opportunity Description

The Indian Health Service (IHS), Office of Clinical and Preventive Services, Division of Nursing Services announces competitive grant applications for Public Health Nurse (PHN) Disease Prevention and Health Promotion (DPHP). This program is authorized by the Snyder Act, 25 U.S.C. 13; Section 301(a), Public Health Service Act, as amended; and Indian Health Care Improvement Act, 25 U.S.C. 1652. This program is described at 93.933 in the Catalog of Federal Domestic Assistance.

The Public Health Nursing (PHN) Service is the prevention of illness, promotion and maintenance of health through the provision of therapeutic services, counseling, education and advocacy services. This is accomplished through assessment and identification of the individual, family and community needs, promotion of consumer participation in establishing health goals, planning programs to meet identified needs and coordination of community health programs and services. The public-health nursing program is flexible and individualized to meet needs within existing resources and takes into account prevailing economic, cultural, social, and geographic characteristics.

Tribal PHN Programs may submit applications for review. The highest scored applications will be funded for two years based on availability of funds and satisfactory progress. The content of the application should relate directly to the basic emphasis of the PHN program's scope of services as indicated by American Nursing Association PHN Standards of Care, Government Performance Results Act (GPRA)

measures associated with PHN practice such as: Alcohol Screening (Fetal Alcohol Syndrome (FAS) Prevention); Domestic (Intimate Partner) Violence Screening; Breast feeding; Childhood Immunization; Adult Immunization; CVD Prevention (Cholesterol Screening); Obesity Assessment; Tobacco Use Assessment; Prenatal Human Immunodeficiency Virus (HIV) Screening; and sound program planning and evaluation principles. Proposal must include measurable health outcomes. Outline goals and anticipated results linked to outcome objectives, process objectives, and proposed activities performed in the home or community setting as demonstrated through quality data improvement of these activities.

II. Award Information

Type of Awards: Grant

Estimated Funds Available: The total amount identified for project period is \$2,352,000. The total for each 12 month period is \$1,176,000. The awards are for 24 months in duration and the average award is approximately \$100,000. Awards under this announcement are subject to availability of funds and satisfactory performance.

Anticipated Number of Awards: 11 awards will be made under the Program.

Project Period: 24 months.

Award Amount: \$100,000 per year.

III. Eligibility Information

1. Eligible Applicants must be one of the following (please specify in the application which category applies to each applicant):

A. Federally-recognized Indian Tribe,
B. Non-Profit Urban Indian Organization as defined by Urbans-25 U.S.C. 1603(f), or

C. Non-Profit Tribal organizations as defined by Indian Health Care Improvement Act (IHICIA), 25 U.S.C. 1603(e).

2. Supporting Documentation to Determine Eligibility:

A. Tribal Resolution—If the applicant is an Indian Tribe or Tribal organization, a resolution from the Tribal government of all Tribes to be served supporting the project must accompany the application submission. Applications by Tribal organizations will be require resolutions if the current Tribal resolutions under which they operate would encompass the proposed activities. In this instance a copy of the current resolution must accompany the application. The list of Tribes to be served by the project in the proposal must match the set of appended resolutions. If a resolution from an appropriate representative of each Tribe