

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB
Display Date 6-19-02
Publication Date 6-20-02
Certifier N. Hawkins

[Docket No. 02N-0264]

**Cooperative Agreement to Support the National Center for Natural Products
Research (NCNPR), University of Mississippi; Intent to Supplement—RFA-CFSAN-02-
5 (CFDA No. 93.103)**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a noncompetitive supplement to the cooperative agreement with 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 \$1 million per annum (direct plus indirect cost). 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.

DATES: Submit the application by *[insert date 30 days after date of publication in the Federal Register]*. If this date falls on a weekend, it will be extended to Monday. If this date falls on a holiday, it will be extended to the following weekday.

ADDRESSES: An application form is available from and should be submitted to: Rosemary Springer, Grants Management Specialist, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182, e-mail rspringe@oc.fda.gov. If the application is hand carried or commercially delivered, it should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20857. Application forms can also be

oc02134

N

found at <http://www.nih.gov/grants/fund/phs398/forms—toc.html>. FDA is unable to receive applications electronically. Do not send the application to the National Institutes of Health, Center for Scientific Research (CSR).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Rosemary Springer (see **ADDRESSES**).

Regarding the programmatic aspects: Jeanne I. Rader, Center for food Safety and Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1786 e-mail: jrader@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION: FDA's authority to enter into grants and cooperative agreements is detailed under section 301 of the Public Health Service 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. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100).

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national effort to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a hard copy of the "Healthy People 2010" objectives, volumes I and II, for \$70 (\$87.50 foreign) S/N 017-000-00550, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Telephone orders can be placed to 202-512-2250. The document is also available in CDX-ROM format, S/N 017-001-00549-5 for \$19 (\$23.50 foreign). This publication is available as well on the Internet at <http://www.health.gov/healthypeople>. Internet reviewers should proceed to "Publications."

I. Restricted Eligibility

On May 3, 2001 (66 FR 22236), FDA announced that a single source application for a cooperative agreement to support the NCNPR at the UM at Oxford, MS would be accepted. Supplemental funding referenced herein will provide for the implementation and enhancement of activities associated with the NCNPR projects described and authorized under the original award FD-U-002071-01 dated September 28, 2001.

II. Availability of Funds

FDA anticipates providing supplemental funding, during the project period, subject to the availability of fiscal year (FY) funding, in an amount up to \$1 million per annum (direct and indirect costs).

The original cooperative agreement was approved for 5 years of funding and currently has 4 years of noncompetitive support remaining, which is contingent upon the availability of FY appropriations and successful performance. FDA anticipates that supplemental funding of the cooperative agreement will commence on or before September 30, 2002.

III. Background

Congress amended the Federal Food, Drug, and Cosmetic Act (the act) with the passage of the Dietary Supplement Health and Education Act of 1994, to create a regulatory framework for dietary supplements under food provisions of the act. FDA has primary responsibility for ensuring that appropriate regulatory actions are taken against marketed products that: (1) Present an unreasonable or significant risk of illness or injury when used according to label directions or under ordinary conditions of use, or (2) bear labeling that is false or misleading.

In the **Federal Register** of May 3, 2001, FDA published a request for a single source application for a cooperative agreement to support the National Center for Natural Products Research, University of Mississippi. FDA awarded the cooperative agreement to the UM-NCNPR on September 28, 2001, following the review of the application by an ad hoc panel of experts

and subsequent approval by the National Advisory Environmental Health Sciences Council in September 2001.

The cooperative agreement between the UM–NCNPR and FDA was established to create a partnership that allows for more efficient use of research resources that identify and analyze specific components in ingredients, including botanical ingredients, thereby enhancing overall public health by ensuring that dietary supplements are safe and their labeling is truthful and not misleading. It also provides opportunities to address important national and international problems in natural products research.

The unique needs for research in support of dietary supplements, with a specific emphasis on the safety of botanical ingredients, has been one of the key reasons for maintaining a strong research program with UM–NCNPR. UM–NCNPR has been determined to be the only institution with the unique capability of providing a broad range of highly relevant scientific expertise and facilities that are physically co-located and singularly dedicated to natural products research. The UM is a comprehensive research institution with numerous academic programs relevant to natural products which can help to ensure that market products are safe for the American public. NCNPR has the unique capability to bring together diverse scientific expertise on bioactive natural products research from: (1) The UM faculty in the School of Pharmacy including researchers in the Departments of Pharmacognosy, Medicinal Chemistry, Pharmaceutics, Pharmacology and the Research Institute of Pharmaceutical Sciences; (2) research scientists in the U.S. Department of Agriculture/Agricultural Research Service's (USDA/ARS) National Products Utilization Research Unit who are physically co-located and programmatically integrated in the NCNPR; and (3) its close academic links and historical collaborations with agriculture and botanical programs and facilities at the UM system. UM–NCNPR's ability to successfully and uniquely collaborate with FDA is also enhanced by its repository of several thousand natural product extracts and its long history of successful basic and applied multidisciplinary research to discover and develop natural

products for use as bioactive ingredients in dietary supplements and pharmaceuticals, and for improving the quality and safety of dietary supplements.

Additionally, research in UM–NCNPR is focused on using state-of-the-art knowledge and technology to discover bioactive natural products, develop novel technologies or processes that facilitate the discovery of bioactive natural products, and provide research-based information on plant-derived products with health applications. These programs, facilities, and expertise working in conjunction with FDA scientists are essential for supporting the needs to ensure that sound science is available for ensuring the safety and truthfulness of labeling of marketed dietary supplement products.

Finally, the large number of established collaborations among UM–NCNPR scientists and other government agencies, academic organizations, and research institutions further enhance the collaboration in the area of natural products research. The primary focus of the FDA and UM–NCNPR collaboration is to support and benefit the public health by promoting more efficient development and dissemination of natural products research and science and to complement the diverse activities of both the public and private sector that may become collaborators.

IV. Purpose

Supplemental funding to FDA's current cooperative agreement will provide the UM–NCNPR with the necessary resources to further conduct research related to the goals of the Dietary Supplement Health and Education Act and to leverage additional resources for natural products research for the benefit of the public health. These resources would:

1. Expand the activities related to the coordination of scientific workshops and conferences, authenticated reference materials, literature reviews, and sharing of technical information;
 2. Augment and enhance overall research by sharing complementary resources with the collaborators by allowing FDA scientists to conduct collaborative research that addresses health issues and emerging health concerns that would improve the overall safety of natural products;
- and

3. Develop additional (new) activities including activities related to investigation of in vitro testing of botanical dietary ingredients.

Innovative activities made possible by supplemental funding will complement existing efforts under FDA's current cooperative agreement with the UM-NCNPR and will provide public health officials at all levels with sound public health information to support policy decisions and enhanced capabilities to communicate with their stakeholders.

V. Substantive Involvement by FDA

All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VI. Review Procedure

The application submitted by the UM-NCNPR will undergo a noncompetitive, dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based on the following evaluation criteria: (1) Responsiveness to RFA, (2) adequacy of plan, (3) timeliness of program implementation, (4) adequacies and availability of research facilities, (5) ability to conduct proprietary research, (6) experience and conclusions, and (7) reasonableness of proposed budget.

If the application is recommended for approval, then it will be presented to the National Advisory Environmental Health Sciences Council.

VII. Reporting Requirement

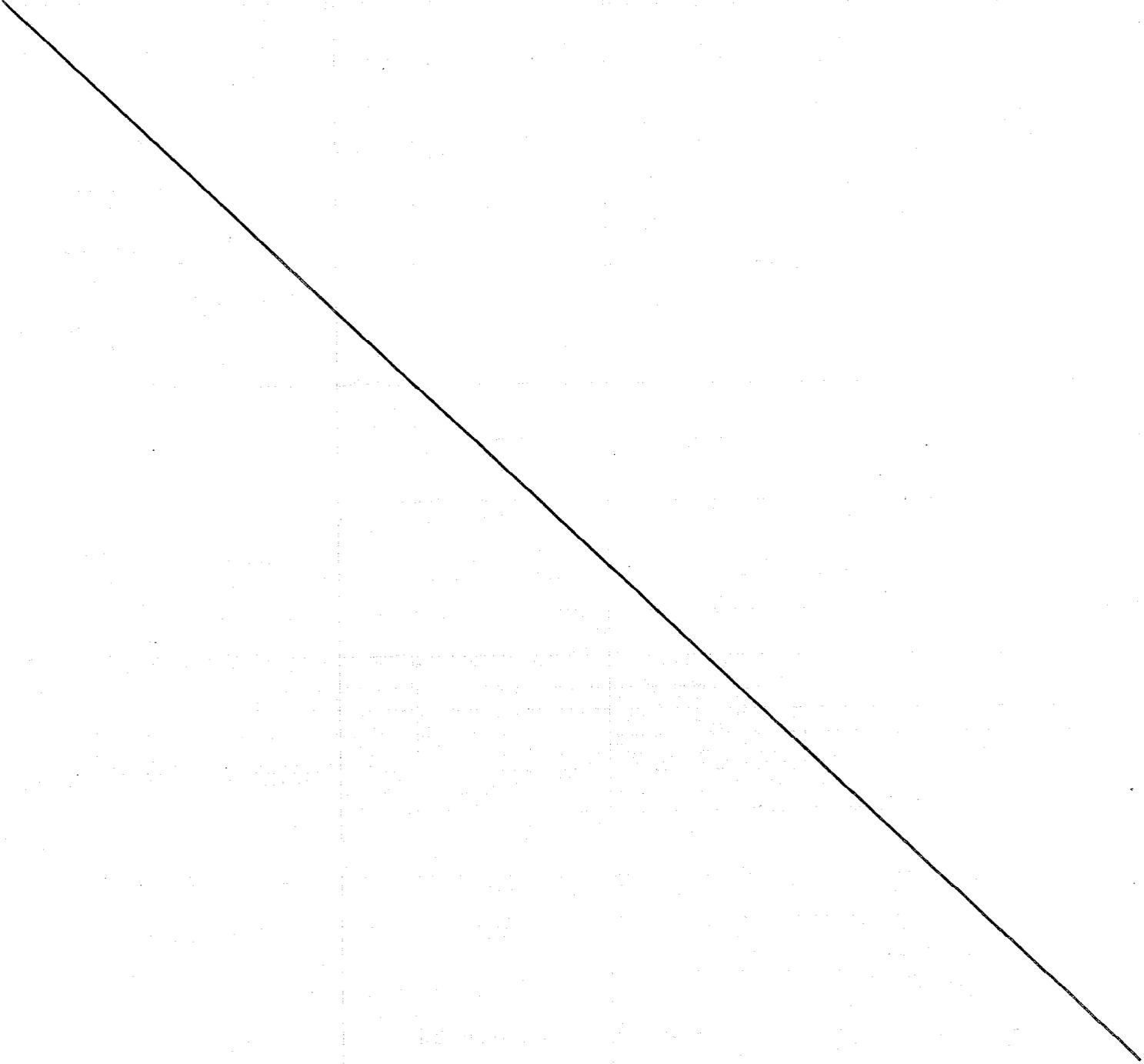
All terms and conditions of the current award shall remain in full force and effect for the supplemental awards.

VIII. Mechanism of Support

Support will be in the form of supplements to FDA's cooperative agreement with the UM-NCNPR. This agreement will be subject to all policies and requirements that govern the research grant program of the PHS, including provisions of 42 CFR part 52 and 45 CFR part 74.

IX. Legend

Data and information included in the application, if identified by the applicant as trade secret or confidential commercial information, will be given confidential treatment as trade secret or



confidential commercial information to the extent permitted by the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Dated: 6-12-02

June 12, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL.**

