

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Nitroxides as Protectors Against Oxidative Stress

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in U.S. Patent 5,792,775, issued on August 11, 1998, entitled "Nitroxides as Protectors Against Oxidative Stress," to Mitos, Inc. having a place of business in the State of California. The field of use may be limited to therapeutics for the treatment and/or protection of tissue damage caused by ionization radiation. The United States of America is the assignee of the patent rights in this invention. This announcement is the first notice to grant an exclusive license to this technology.

**DATES:** Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before June 27, 2005 will be considered.

**ADDRESSES:** Requests for a copy of the patent, inquiries, comments and other materials relating to the contemplated license should be directed to: Pradeep Ghosh, J.D., Ph.D., M.B.A., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; telephone: (301) 435-5282; Facsimile: (301) 402-0220; e-mail: [ghoshpr@mail.nih.gov](mailto:ghoshpr@mail.nih.gov)]

**SUPPLEMENTARY INFORMATION:** This technology relates to the use of a biologically compatible composition containing an effective amount of a metal independent nitroxide compound as an antioxidant capable of protecting cells, tissues, organs, and whole organisms against deleterious effects of harmful oxygen-derived species generated during oxidative stress

induced by ionizing radiations. Nitroxides are low molecular weight molecules and easily soluble in aqueous solutions. They are active within the biological pH range of 5-8, non-toxic at effective concentrations and can be easily attached to several organic molecules that may facilitate targeting of the molecules to specific organs or organelles. These properties of nitroxides make them ideal for treatment and protection of radiation induced cellular and tissue damages.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 18, 2005.

**Steven M. Ferguson,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

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

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information

on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are 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 through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: 2005 Client/Patient Sample Survey—New

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) will conduct a sample survey of mental health programs (*i.e.*, inpatient, residential, and less than 24-hour care) within specialty mental health organizations. These organizations include psychiatric hospitals, general hospitals with separate psychiatric services, multiservice mental health organizations, residential treatment centers, and freestanding outpatient clinics and partial care organizations.

A sample of approximately 2,500 mental health organizations/programs will provide information on an average sample of 8 admissions and 8 persons under care in the programs. National estimates will be generated on the number of persons admitted to and under care in these organizations, and on the sociodemographic, clinical, and service use characteristics of these persons. This survey will update a previous sample survey conducted in 1997 (OMB No. 0930-0114).

In addition, the 2005 survey will include a consumer survey for the sampled adults under care in the less than 24-hour programs to obtain consumers' perceptions of care received. Respondents will have the option of responding electronically.

The annual burden estimate is shown below:

Respondent	No. of respondents	No. of responses per respondent	Average burden/response (hrs.)	Total annual burden (hrs.)
Mental Health Organization/Program .....	2,500	1	5.25	13,125
Consumer .....	8,000	1	0.25	2,000
Total .....	10,500	.....	.....	15,125

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, 1 Choke Cherry Road, Rockville, MD 20850. Written comments should be received by June 27, 2005.

Dated: April 12, 2005.

**Anna Marsh,**

*Executive Officer, SAMHSA.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

#### Proposed Project: Emergency Response Grants Regulations—42 CFR Part 51—(OMB No. 0930-0229)—Extension

This rule implements section 501(m) of the Public Health Service Act (42 U.S.C. 290aa), which authorizes the Secretary to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities. The rule establishes criteria for determining that a substance abuse or mental health emergency exists, the minimum content for an application, and reporting requirements for recipients of such funding. SAMHSA will use the information in the applications to make a determination that the requisite need exists; that the mental health and/or substance abuse needs are a direct result of the precipitating event; that no other local, State, tribal or Federal funding sources are available to address the need; that there is an adequate plan of services; that the applicant has appropriate organizational capability; and, that the budget provides sufficient justification and is consistent with the documentation of need and the plan of services. Eligible applicants may apply to the Secretary for either of two types of substance abuse and mental health emergency response grants: Immediate awards and Intermediate awards. The

former are designed to be funded up to \$50,000, or such greater amount as determined by the Secretary on a case-by-case basis, and are to be used over the initial 90-day period commencing as soon as possible after the precipitating event; the latter awards require more documentation, including a needs assessment, other data and related budgetary detail. The Intermediate awards have no predefined budget limit. Typically, Intermediate awards would be used to meet systemic mental health and/or substance abuse needs during the recovery period following the Immediate award period. Such awards may be used for up to one year, with a possible second year supplement based on submission of additional required information and data. This program is an approved user of the PHS-5161 application form, approved by OMB under control number 0920-0428. The quarterly financial status reports in 51d.10(a)(2) and (b)(2) are as permitted by 45 CFR 92.41(b); the final program report, financial status report and final voucher in 51d.10(a)(3) and in 51d.10(b)(3-4) are in accordance with 45 CFR 92.50(b). Information collection requirements of 45 CFR part 92 are approved by OMB under control number 0990-0169. The following table presents annual burden estimates for the information collection requirements of this regulation.

42 CFR citation	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Immediate award application:				
51d.4(a) and 51d.6(a)(2) .....	3	1	3	*9
51d.4(b) and 51d.6(a)(2), Immediate Awards .....	3	1	10	*30
51d.10(a)(1)—Immediate awards—mid-program report if applicable .....	3	1	2	*6
Final report content for both types of awards:				
51d.10(c) .....	6	1	3	18
Total .....	6	.....	.....	18

\* This burden is carried under OMB No. 0920-0428.

Written comments and recommendations concerning the proposed information collection should be sent by May 26, 2005 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC

20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: (202) 395-6974.

Dated: April 14, 2005.

**Anna Marsh,**

*Executive Officer, SAMHSA.*

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