1998, and now U.S. Patent 6,132,980 which issued on October 17, 2000; S/N 09/162,368 (DIV of 08/725,736), filed on September 28, 1998, and now U.S. Patent 6,083,703 which issued on July 4, 2000; and S/N 09/651,210 (DIV of 08/725,736), filed on August 30, 2000, all entitled ''Identification of TRP–2 as a New Human Tumor Antigen Recognized by Cytotoxic T Lymphocytes' and PCT Patent Application PCT/US97/02186 (based upon U.S. Patent Applications S/N 08/599,602 and 08/725,736) filed on February 6, 1997, entitled ''Human Cancer Antigen of Tyrosinase-Related Protein 1 and 2 and Genes Encoding Same'', to Mojave Therapeutics, Inc. of Tarrytown, New York. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to gp100 and/or TRP–2 peptides, proteins, glycoproteins, and/or polynucleotides which are covalently or non-covalently bound to heat shock proteins for use as immunotherapeutic vaccines against melanoma in humans, and specifically excluding the use of gp100 and/or TRP–2 in any other manner or form.

DATES: Only written comments and/or license applications which are received by the National Institutes of Health on or before October 12, 2001 will be considered.

ADDRESSES: Requests for copies of the patent/patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Elaine White, 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) 496–7056, x282; Facsimile (301) 402–0220; E-mail eg46t@nih.gov.

SUPPLEMENTARY INFORMATION: 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 sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted 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: August 2, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–20195 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is proposing to amend Appendix B–I of the NIH Guidelines to establish criteria for designating strains of *E. coli* as risk group 1 agents.

DATES: The public is encouraged to submit written comments on the proposed change. Comments may be submitted to the NIH Office of Biotechnology Activities (OBA) in paper or electronic form. Comments received on or before September 12, 2001 will be considered by NIH. All comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892–7985, 301–496–9838, weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or want additional information about these proposed changes, please contact OBA by e-mail at *oba@od.nih.gov,* or telephone at 301–496–9838. Comments can be submitted to the same e-mail address, by fax to 301–496–9839, or mail to the Office of Biotechnology Activities address set forth above.

SUPPLEMENTARY INFORMATION: The University of Florida has asked OBA to set the risk group level for strain B of the common bacterium *E. coli,* which is non-virulent. Strain B is widely used in industry for large-scale work (greater than 10 liters of culture) due to increased stability of cloned sequences in this strain versus *E. coli* K–12. Currently, the only non-virulent strain of *E. coli* designated as a risk group 1 agent (agents not associated with disease in healthy adult humans) in the NIH Guidelines is strain K–12. Potentially pathogenic strains of E. coli are designated as risk group 2 agents in the NIH Guidelines.

At the March 2001 RAC meeting, a recommendation was made to define the criteria for designating strains of *E. coli* as risk group 1 agents. The establishment of general criteria is preferable to narrowly addressing a single strain. The suggested criteria were: ''(1) they [the *E. coli* strain] carry deletions in metabolic genes to engender the requirement for specialized laboratory media; and (2) they do not pose a threat of disease: they do not carry any active virulence markers nor do they make any toxins (nor do they carry the genes for these toxins).''

Following the March 2001 meeting, the University of Florida Institutional Biosafety Committee responded that the investigator, Dr. Luli (Adjunct Professor in Microbiology and Cell Science at the University of Florida and also Research Director for BC International Corp.), who made the initial request had reservations regarding the requirement for deletions in metabolic genes. Dr. Luli stated that the use of specialized laboratory media would pose a problem for large-scale, industrial work. Dr. Luli suggested that instead of an absolute requirement for specialized laboratory media, that the ''* * * scope of the [first] requirement be broadened to simply demonstrate ''crippled'' or adversely affected metabolism.'' The rationale for this modification is that the strains of *E. coli* B that Dr. Luli proposes to use have reduced growth rates compared to wild type *E. coli* even in complete, rich laboratory media.

The proposed criteria for designating an *E. coli* strain as a risk group 1 agent were revisited at the June 2001 RAC meeting. *Ad hoc* consultant, Dr. James Kaper, University of Maryland School of Medicine, also participated in the RAC review and discussion. During the June meeting discussion, it was pointed out that a growth requirement is not a current criteria in the NIH Guidelines for designation of *E. coli* K–12 as a risk group 1 agent. Accordingly, the criteria for designating strains of *E. coli* as risk group 1 agents were revised as follows: ''(1) they [the *E. coli* strain] do not possess a complete lipopolysaccharide (i.e., they lack the O antigen and have a ''rough'' colony morphology); and (2) they do not carry any active virulence factors—such as—toxin, or colonization factors nor do they carry genes for these factors.'' A ''rough'' colony morphology is indicative of the absence of a

complete coat that aids in survival in the intestine and environment.

The proposed use of general criteria for designating strains of *E. coli* as risk group 1 agents is not intended to eliminate the need for case-by-case consideration of the potential effects of a biological agent on those who may be exposed to it (Section II–A–2 of the NIH Guidelines) and any general criteria will be subject to reevaluation and change in light of evidence that a strain meeting those criteria is associated with disease in healthy adult humans.

Proposed Amendments to the NIH Guidelines

For the reasons stated above, it is proposed to amend Appendix B–I, Risk Group (RG1) Agents, to state:

Appendix B–I. Risk Group (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis* (see Appendix C–IV–A, *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems, Exceptions); adeno-associated virus (AAV) types 1 through 4; and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of *Escherichia coli* (see Appendix C–II–A, *Escherichia coli* K–12 Host Vector Systems, Exceptions) is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (i.e., lacks the O antigen and has a ''rough'' colony morphology); and (2) does not carry any active virulence factor (e.g., toxins) or colonization factors and does not carry any genes encoding these factors.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

Dated: August 3, 2001.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–20191 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Continuation of the Cooperative Agreement for the State Treatment Outcomes and Performance Pilot Studies Enhancement Technical Assistance Center

AGENCY: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Continuation of the cooperative agreement with the State Treatment Outcomes and Performance Pilot Studies Enhancement Technical Assistance Center Grantee, Johnson, Bassin and Shaw, Incorporated, for one year.

SUMMARY: This notice is to inform the public of the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment's (CSAT) planned award to Johnson, Bassin and Shaw (JBS), Inc., to continue to serve as the Technical Assistance Center for the State Treatment Outcomes and Performance Pilot Studies Enhancement (TOPPS II) cooperative agreement program for one year. An additional year of support is needed to provide detailed statistical analyses of the final data set, to develop comprehensive written reports laying out the complete final analyses and results, and to translate the results into written and oral forms that can be understood and used by the substance abuse treatment field. In fiscal year 2001, CSAT plans to make approximately $380,000 available for the award to JBS, Inc. The award will be made if the application is scored by the initial review group and concurred with by the CSAT National Advisory Council.

Eligibility for the cooperative agreement is limited to JBS, Inc., Only JBS, Inc., may apply because they have served as the Technical Assistance Center for the multi-site study during the past 2+ years of data collection. They developed the necessary infrastructure for the collection, analysis and dissemination of TOPPS II project data, and have experience working with the current 16 TOPPS II single State agency grantees. JBS, Inc., designed and maintains the TOPPS II database, collects and cleans the grantees' admission and discharge data, and is currently receiving and processing follow-up data. It would be an impediment to the orderly conduct of the study if there were a disruption in data collection and analyses. JBS, Inc., has hired competent and capable staff with experience in conducting large, prospective, multi-site, substance abuse services performance and outcome studies. The incumbent works collaboratively with Federal and State staff, and members of the TOPPS II Steering Committee to facilitate the development of the TOPPS II data collection protocols, and to develop instruments and protocols for performance and outcome measurement, data quality management, secondary data analysis, statistical analysis and technical report writing.

Because of the incumbent's experience with this initiative, JBS, Inc., is uniquely positioned to guide the overall effort and to integrate the work of the TOPPS II study sites into a conceptual whole. To compete this announcement otherwise, would be duplicative and inefficient. Therefore, the eligibility for a continuation cooperative agreement with SAMHSA/CSAT is being limited to the incumbent, JBS, Inc.

Authority: The cooperative agreement with JBS, Inc., will be made under the authority of section 1935 (b)(1)(C) of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.238.

CONTACT: Hal Krause, CSAT, SAMHSA, Rockwall II, Suite 880, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–0488; e-mail: hkrause@samhsa.gov.

Dated: August 7, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–20162 Filed 8–10–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2002 Funding Opportunities

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of funds for grants for the following activity. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Guidance for Applicants (GFA), including Part I, A Cooperative