

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	135	1	135	80	10,800
Total					10,800

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

TABLE 7—ESTIMATED ANNUAL TOTAL REPORTING BURDEN FOR ALL CENTERS ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d)	3,586	13,998	108,300
25.40(a) and (c)	190	190	80,130
Total					188,430

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

Dated: February 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03836 Filed 2-19-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of MUC-1 Tumor Associated Antigens as Cancer Vaccines for Bladder Cancer, Breast Cancer, Colorectal Cancer, Gastric Cancer, Kidney Cancer, Liver Cancer, Lung Cancer, Ovarian Cancer, Prostate Cancer and Pancreatic Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics (“BNIT”) located in Mountain View, CA, USA:

Intellectual Property: U.S. provisional patent application no. 61/582, 723 filed January 3, 2012 entitled “Native and Agonist CTL Epitopes of the MUC-1 Tumor Antigen” [HHS Ref. No. E-001-2012/0-US-01] as well as all international applications, continuation applications and divisional applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights for development of Pox-virus based vaccines for bladder cancer, breast cancer, colorectal cancer, gastric cancer, kidney cancer, liver cancer, lung cancer, ovarian cancer, prostate cancer and pancreatic cancer.”

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 22, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; Email: *chatterjeesa@od.nih.gov*.

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction. The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/major histocompatibility complex and the second or “co-stimulatory” signal is required for cytokine production,

proliferation, and other aspects of T-cell activation.

Dr. Jeffrey Schlom et al. at NCI have identified 7 new agonist epitopes of the MUC-1 tumor associated antigen. Compared to their native epitope counterparts, peptides reflecting these agonist epitopes have enhanced ability to generate cytotoxic T-lymphocytes (CTL), which in turn have a greater ability to kill MUC-1 expressing human tumor cells. The agonist epitopes span both the VNTR region of MUC-1 and the C-terminus region. The epitopes encompass two major MHC alleles reflecting the majority of the population.

Along with the method of use, the technology encompasses the use of these agonist epitopes in peptide- and protein-based vaccines, with dendritic cells or other antigen presenting cells, or encoding sequences in DNA, viral, bacterial, yeast, or other types of vectors, or to stimulate T-cells in vitro for adoptive immunotherapy protocols.

The MUC-1 tumor associated antigen has been shown to be overexpressed and/or underglycosylated in a wide range of human cancers. The C-terminus region of MUC-1 (MUC-1C) has been shown to be an oncogene and has been associated with a more aggressive phenotype in several different cancers.

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 Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the 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 Part 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: February 13, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013-03799 Filed 2-19-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Translational Research in Diabetes, Obesity and Endocrinology Disorders.

Date: March 13, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nancy Sheard, SCD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046-E, MSC 7892, Bethesda, MD 20892, 301-408-9901, sheardn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell, Computational, and Molecular Biology.

Date: March 13, 2013.

Time: 10:00 a.m. to 6:00 p.m..

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Maria DeBernardi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7892, Bethesda, MD 20892, 301-435-1355, debernardima@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Population Studies and Epidemiology AREA Review.

Date: March 13, 2013.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Heidi B Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301-379-5632, hfriedman@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA: Endocrinology, Metabolism Nutrition and Reproduction.

Date: March 13, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154 dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Biophysical and Biomechanical Aspects of Embryonic Development.

Date: March 13, 2013.

Time: 1:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rass M Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, shayiqr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Diabetes, Metabolism and Obesity.

Date: March 13, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, gary.hunnicutt@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR10-234: Bioengineering Research Partnership (BRP).

Date: March 13, 2013.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ping Fan, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892, 301-408-9971, fanp@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 13, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-03802 Filed 2-19-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group Training and Workforce Development Subcommittee D.

Date: March 14-15, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18C, Bethesda, MD 20892, 301-594-2771, johnsonrh@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical