H. Combination Product Regulation

For some types of combination products, the CDER–CDRH ICA addresses good manufacturing practices, registration and listing, labeling, and other product regulation issues. The agency is developing guidance and/or regulations to address these and other significant areas of combination product regulation, and when final, these documents will ultimately update the limited information provided in the CDER–CDRH ICA on these topics.

VI. Practices Specific to Assignment of Combination Products

The agency has reviewed its practices specific to the assignment of combination products to ensure that they are in compliance with the requirement of section 503(g)(4)(B) of the act that the agency promptly assign a combination product to an agency center with primary jurisdiction in accordance with section 503(g)(1) of the act.

The agency has refined its processing of jurisdictional requests to ensure that the agency makes its assignments promptly. For example, section 503(g)(4)(A) of the act requires OCP, in determining whether a product is appropriately classified as a combination product, to consult with the component within the Office of the Commissioner that is responsible for such determinations. In the **Federal Register** of June 23, 2003 (68 FR 37075), the agency issued a final rule announcing that to enhance the efficiency of agency operations, OCP assumed responsibility from the Office of the Ombudsman for designating the component of FDA with primary jurisdiction for the premarket review and regulation of any product requiring a jurisdictional determination under part 3 (21 CFR part 3). This change consolidated the jurisdiction program within OCP, eliminated the requirement for consultation about the classification of a product as a combination product, and made the RFD program more efficient to administer. The final rule also provided for the electronic submission of RFDs (§ 3.7(d)).

Similarly, OCP has refined its internal processes and practices to ensure that all RFDs are resolved within the 60-day timeframe requirement of section 563(b) of the act (21 U.S.C. 360bbb–2(b)) (§ 3.8(b)). All RFDs submitted to OCP since its inception have been resolved within the 60-day period. Furthermore, all requests for reconsideration were responded to within the 15-day timeframe (§ 3.8(c)). For the period from the establishment of OCP through March 31, 2006, FDA's average RFD processing time for assignments of combination products is 37.7 days (median 40 days, range 11–59 days). Accordingly, the agency has preliminarily determined that its practices are consistent with the requirement contained in section 503(g)(4)(B) of the act that it promptly assign combination products to an agency center based on the product's PMOA. FDA plans to continue in effect the process improvements needed to maintain the prompt assignment of combination products, and plans to continue to work to refine its processes further.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–15967 Filed 9–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Mammalian Cell Surface Display of Fvs for Rapid Antibody Maturation

Description of Technology: This technology describes a new method of cell surface display of single chain antibodies for affinity maturation in a mammalian system. Cells expressing a rare mutant antibody with higher affinity were enriched about 240 fold by a single-pass cell sorting from a large excess of cells expressing wild-type antibodies with slightly lower affinity. Additionally, a highly enriched mutant with increased binding affinity for CD22 after a single selection of a combinatory library randomizing an intrinsic antibody hotspot was successfully obtained. The system is compatible with other mammalian expression systems and it is a rapid, simple and robust procedure. The method can be useful in isolating high affinity antibodies for cancer, AIDS and other diseases.

Applications: (1) A new method of displaying Fvs on human cells; (2) A new method useful to isolate new high affinity antibodies for cancer, AIDS and other diseases.

Market: The method has a potential several billion dollar market as it can be potentially used in immunotherapeutic approaches for the treatment of cancer, AIDS and other diseases.

Development Status: The technology is currently in pre-clinical stage of development.

Inventors: Drs. Ira Pastan and Mitchell Ho (NCI).

Publication: Mo Ho, S Nagata, I Pastan. Isolation of anti-CD22 Fv with high affinity by Fv display on human cells. Proc Natl Acad Sci USA. Jun 20;103(25):9637–9642. Epub 2006 Jun 8, doi 10.1073/pnas.0603653103.

Patent Status: U.S. Provisional Application No. 60/794,212 filed 21 Apr 2006 (HHS Reference No. E–200–2006/0–US–01)

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Jesse S. Kindra, J.D.; 301/435–5559; *kindraj@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Mammalian Cell Surface Display of Fvs

for Rapid Antibody Maturation. Please contact Betty Tong, PhD at 301–496–0477 or *tongb@mail.nih.gov* for more information.

Methods of Identifying and Treating Tumors that Express Erythropoietin Receptor Protein (EPO R)

Description of Invention: The inventors have discovered that EPO and EPOR are co-expressed in tumors of von Hippel-Lindau (VHL) patients and in tumors of sporadic renal tumor patients. Ligands that bind to EPOR but do not activate the receptor can target specific tumor cells with minimal detrimental effect on normal cells.

Applications: (1) Treatment and diagnosis of renal tumors in sporadic and kidney dialysis patients; (2) Treatment and diagnosis of multiple tumors in different organs in patients with von Hippel-Landau patients; (3) Treatment and diagnosis of pheochromocytomas; (4) Treatment and diagnosis of eye and CNS hemangioblastomas.

Inventors: Zhengping Zhuang *et al.* (NINDS).

Patent Status: International Patent Application No. PCT/US2005/033850 filed 20 Sep 2005, which published as WO 2006/034354 on 30 Mar 2006 (HHS Reference No. E–274–2004/0–US–02).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Thomas P. Clouse, J.D.; 301/435–4076; *clouset@mail.nih.gov.*

Collaborative Research Opportunity: In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors. For further information regarding collaborative research opportunities, please contact Dr. Martha Lubet at e-mail: *lubetm@mail.nih.gov* or telephone: 301/435–3120.

Diagnostic and Therapeutic Use of SPANX–N Genes in Cancer and Fertility

Description of Technology: Cancer is the second leading cause of death in United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2006. In spite of the success of cancer screening and early diagnosis cancer still remains a life threatening disease. There is a great need for the development of new markers and new therapeutic strategies that would more accurately predict the outcome of the disease and aid in the proper management of cancer. Antibody-based strategies have taken a lead among the new cancer therapeutic approaches.

This technology describes the identification of the link between expression of individual members of the SPANX-gene cluster and malignancies including prostate cancer. SPANX-genes consist of two subfamilies, SPANX–A/D and SPANX–N1/N5. The invention provides SPANX polypeptides, nucleic acids and antibodies that could be useful for detecting and treating prostate or other cancers. The SPANX–N genes are a family of related genes that are expressed in normal testis and in tumor cells in humans including melanoma, bladder carcinomas and myelomas. The SPANX cancer/testis antigens thus represent good candidates for diagnosis or treatment of several cancers. The present invention also describes a new approach for mutation screen of the SPANX gene cluster, including gene amplification, linking predisposition to prostate cancer with a specific architecture of the SPANX gene cluster. Additionally, due to the differential localization of SPANX-proteins in the spermatozoa, the mutational screen can be also used for diagnostics of infertility. Developed antibodies against SPANX–A/D and SPANX–N1/N5 proteins can be used for (i) diagnostics of cancer, (ii) diagnostics of infertility and iii) for the development of new contraceptives.

Applications: (1) Novel antibodies to SPANX–A/D and SPANX–N1/N5; (2) New approach for mutation screen of SPANX gene cluster; (3) Antibodies can be used for diagnosis and development of immunotherapeutics for several cancers including prostate; (4) Compounds can also be used for the diagnosis of infertility and development of new contraceptives.

Market: (1) 600,000 deaths from cancer related diseases estimated in 2006; (2) The technology platform involving novel antibodies for the diagnosis and therapeutics of several cancers has a potential market of more than 7 billion U.S. dollars; (3) The technology platform has additional market in fertility related diagnostics and therapeutics.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Natalay Kouprina (NCI) *et al.*

Publications:

1. N Kouprina *et al.* The SPANX gene family of cancer/testis-specific antigens: rapid evolution and amplification in African great apes and hominids. Proc Natl Acad Sci USA. 2004 Mar 2;101(9):3077–3082. Epub 2004 Feb 18, doi 10.1073/pnas.0308532100.

2. N Kouprina *et al.* Dynamic structure of the SPANX gene cluster mapped to the prostate cancer susceptibility locus HPCX at Xq27. Genome Res. 2005 Nov;15(11):1477–1486.

3. N Kouprina and V Larionov. TAR cloning: Insights into gene function, long-range haplotypes, and genome structure and evolution. Nature Reviews Genetics, 7: In press, 2006.

4. N Kouprina *et al.* SPANX–N gene cluster at Xq27: A new group of cancer-testis antigen genes encoding acrosomal proteins. Submitted to Cancer Research, 2006.

Patent Status: U.S. Provisional Application No. 60/636,811 filed 15 Dec 2004 (HHS Reference No. E–212–2004/0–US–01); PCT Application No. PCT/US2005/045317 filed 15 Dec 2005, which published a WO 2006/065938 on 22 Jun 2006 (HHS Reference No. E–212–2004/1–PCT–01)

Licensing Status: Available for exclusive and non-exclusive licensing.

Licensing Contact: Mojdeh Bahar, J.D.; 301/435–2950; *baharm@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Biosystems and Cancer is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this new diagnostic marker for malignancy and infertility and new targets for immuno-cancer therapy. Please contact Betty Tong, Ph.D. at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Cancer Peptides of NY–ESO–1/CAG–3

Description of Technology: The current invention embodies the identification, isolation and cloning of a gene encoding a novel tumor antigen, NY ESO–1/CAG–3, as well as cancer peptides thereof and antigenic cancer epitopes contained within the cancer peptides. This novel antigen is recognized by cytotoxic T lymphocyte clones derived from the TIL586 (tumor infiltrating lymphocyte) cell line in an HLA restricted manner.

The inventors believe that cancer peptides which are encoded by the NY ESO–1/CAG–3 gene represent potential cancer vaccines, protecting an individual from development of cancer by inhibiting the growth of cells or tumors which express the NY ESO–1/CAG–3 antigen. Also embodied in the invention are pharmaceutical compositions comprising the NY ESO–1/CAG–3 antigen, peptide, or an antigenic cancer epitope thereof in combination with one or more immunostimulatory molecules. These compositions represent potential anticancer therapeutics, stimulating NY

ESO–1/CAG–3-specific T cells to elicit an anti-cancer immunogenic response and thereby eliminating or reducing the cancer. While these vaccines and pharmaceutical compositions may be developed for use against a variety of cancers, data obtained to date indicate that they may be of particular value for use against melanoma.

Methods for diagnosing cancer via the detection of NY ESO–1/CAG–3 are also embodied in the invention.

Inventors: Steven A. Rosenberg (NCI) *et al.*

Patent Status: U.S. Patent No. 7,084,239 issued 01 Aug 2006 (HHS Reference No. E–265–1997/0–US–04).

Licensing Status: Available for non-exclusive licensing or exclusive licensing.

Licensing Contact: Jesse S. Kindra, J.D.; 301/435–5559; *kindraj@mail.nih.gov.*

Dated: September 20, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–15975 Filed 9–27–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the NIH Advisory Board for Clinical Research, September 29, 2006, 10 a.m. to September 29, 2006, 2 p.m. National Institutes of Health, Building 10, 10 Center Drive, 4–2551, CRC Medical Board Room, Bethesda, MD 20892 which was published in the **Federal Register** on September 8, 2006, FR 06–7534.

The open session will occur from 10 a.m.–1:30 p.m. The closed session will begin approximately at 1:30 p.m. and run until 2 p.m. The meeting will be held in the Clinical Center, Bldg. 10, Rm. 4–2551, CRC Medical Board Room. The meeting is partially Closed to the public.

Dated: September 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8329 Filed 9–27–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; Basic Science.

Date: October 23–24, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Dale L. Birkle, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 451–6570, *birkled@mail.nih.gov*.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Research.

Date: October 30–31, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Jeanette M. Hosseini, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–9096, *jeanetteh@mail.nih.gov*.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Research Huntington's Disease.

Date: October 31, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Jeanette M. Hosseini, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–9096, *jeanetteh@mail.nih.gov*.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel; Developmental Centers for Research on CAM.

Date: November 16–17, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda, Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Martina Schmidt, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–3456, *schmidma@mail.nih.gov*.

Dated: September 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8328 Filed 9–27–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 contract proposals and discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which wouldconstitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Tropical Medicine Research Centers.

Date: October 16–18, 2006.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Gary S. Madonna, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/