Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health, Labor and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 3:45 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 7, 2004, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on May 3, 2004, via the Internet at *http://www.fda.gov/cder/meeting/ICH__05172004.htm.*

Dated: April 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9323 Filed 4–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–0529]

Guidance for Industry on Changes to an Approved New Drug Application or Abbreviated New Drug Application; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 8, 2004 (69 FR 18768). The document announced the availability of a revised guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' The document was published with inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–7533, appearing on page 18768 in the **Federal Register** of Thursday, April 8, 2004, the following corrections are made:

1. On page 18768, in the first column, under the **FOR FURTHER INFORMATION CONTACT** section, the contact information is corrected to read ''David J. Cummings, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5187.''

2. On page 18768, in the third column, the second full paragraph is removed.

Dated: April 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9324 Filed 4–23–04; 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.

Reactivity of Human Sera in a Sensitive, High Throughput Pseudovirus-Based Papillomavirus Neutralization Assay for HPV 16 and HPV 18

John Schiller (NCI), Douglas Lowy (NCI), Chris Buck (NCI),

Diana Pastrana (NCI), Richard Roden (EM), DHHS Reference No. E–137–2004/0—Research Material

Licensing Contact: Peter Soukas; (301) 435–4646; *soukasp@mail.nih.gov.*

This invention is a research tool for measuring protective antibody responses generated by prophylactic Human Papilloma Virus (HPV) vaccines. Sensitive high-throughput neutralization assays, based upon pseudoviruses carrying a secreted alkaline phosphatase (SEAP) reporter gene, were developed and validated by the inventors for HPV 16, HPV 18, and bovine papillomavirus 1 (BPV1). In a 96-well plate format, the assay was reproducible and appears to be as sensitive as, but more specific than, a standard papillomavirus-like particle (VLP)-based enzyme-linked immunosorbent assay (ELISA). The SEAP pseudovirus-based neutralization assay should be a practical method for quantifying potentially protective antibody responses in HPV natural history and prophylactic vaccine studies.

This assay is available nonexclusively through a biological materials license. The assay is further described in Pastrana *et al.*, ''Reactivity of human sera in a sensitive, high-throughput pseudovirus-based papillomavirus neutralization assay for HPV16 and HPV18,'' *Virology.* 2004 Apr 10;321(2):205–16.

Enzymatically-Active RNA-Dependent RNA Polymerase From a Human Norovirus (Calicivirus)

Gael Belliot, Stanislav Sosnovtsev, Kyeong-Ok Chang, Kim Green (NIAID),
DHHS Reference No. E–283–2003/0—Research Material.

Licensing Contact: Peter Soukas; (301) 435–4646; *soukasp@mail.nih.gov.*

The noroviruses (formerly known as ''Norwalk-like viruses'') are associated with gastroenteritis outbreaks, affecting large numbers of individuals each year. Emerging data are supporting their increasing recognition as important agents of diarrhea-related morbidity and mortality. The frequency with which noroviruses are associated with gastroenteritis as ''food and water-borne pathogens'' has led to the inclusion of caliciviruses as Category B Bioterrorism Agents/Diseases. Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is to development of molecular biology-based tools and replication systems. This invention reports the isolation of the first recombinant, enzymatically-active proteinase and RNA dependent RNA polymerase (RdRp) complex for a human norovirus. This enzyme should facilitate studies aimed at developing therapeutic drugs for norovirus disease.

The materials embodied in this invention are available nonexclusively through a biological materials license. The materials are further described in Wei L *et al.*, ''Proteinase-polymerase precursor as the active form of feline calicivirus RNA-dependent RNA polymerase,'' *J. Virol.* 2001 Feb;75(3):1211–9.

Construction of an Infectious Full-Length cDNA Clone of the Porcine Enteric Calicivirus RNA Genome

Kyeong-Ok Chang (NIAID), Stanislav Sosnovtsev (NIAID), Gael Belliot (NIAID), Linda Saif (EM), Kim Green (NIAID) DHHS Reference No. E–214–2003/0—Research Material

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov.*

Porcine enteric calicivirus (PEC) is a member of the genus Sapovirus in the family Caliciviridae. This virus causes diarrheal illness in pigs, and is presently the only enteric calicivirus that can be grown in cell culture. In addition to its relevance to veterinary medicine as a diarrheal agent in pigs, PEC serves as an important model for the study of enteric caliciviruses that cause diarrhea and that cannot be grown in cell culture (including the noroviruses represented by Norwalk virus). The development of an infectious cDNA clone is important because it enables the use of ''reverse genetics'' to engineer mutations of interest into the genome of PEC and to study their effects. In addition, it allows the introduction of foreign coding sequences into the genome of PEC that could be useful for vaccine development in swine and possibly humans. This discovery has both basic research applications such as mapping mutations involved in tissue culture adaptation, tissue tropism, and virulence as well as practical applications such as providing a genetic backbone for the development of chimeric vaccine viruses.

The materials embodied in this invention are available nonexclusively through a biological materials license. The materials are further described in Chang K–O *et al.*, ''Cell-culture propagation of porcine enteric calicivirus mediated by intestinal contents is dependent on the cyclic AMP signaling pathway,'' *Virology.* 2002 Dec 20;304(2):302–10.

Construction of Recombinant Baculoviruses Carrying the Gene Encoding the Major Capsid Protein, VP1, From Calicivirus Strains (Including Norovirus Strains Toronto, Hawaii, Desert Shield, Snow Mountain, and Md145–12)

Kim Green, Judy F. Lew, Adriene D. King, Stanislav Sosnovtsev, Gael Belliot (NIAID) DHHS Reference No. E–198–2003/0—Research Material

Licensing Contact: Peter Soukas; 301/435–4646; soukasp@mail.nih.gov.

The noroviruses (known as ''Norwalk-like viruses'') are associated with an estimated 23,000,000 cases of acute gastroenteritis in the United States each year. Norovirus illness often occurs in outbreaks, affecting large numbers of individuals, illustrated recently by well-publicized reports of gastroenteritis outbreaks on several recreational cruise ships and in settings such as hospitals and schools. Norovirus disease is clearly important in terms of medical costs and missed workdays, and accumulating data support its emerging recognition as important agents of diarrhea-related morbidity.

Because the noroviruses cannot be propagated by any means in the laboratory, an important strategy in their study is the development of molecular biology-based tools. This invention reports the development of recombinant baculoviruses carrying the capsid gene from several caliciviruses associated with human disease. Growth of these baculovirus recombinants in insect cells results in the expression of virus-like particles (VLPs) that are antigenically indistinguishable from the native calicivirus particle. These VLPs can be purified in large quantities for use as diagnostic reagents and potential vaccine candidates.

The materials embodied in this invention are available nonexclusively through a biological materials license. An example of the application of these materials is further described in Green KY *et al.*, ''A predominant role for Norwalk-like viruses as agents of epidemic gastroenteritis in Maryland nursing homes for the elderly,'' *J. Infect. Dis.* 2002 Jan. 15;185(2):133–46.

MVA Expressing Modified HIV envelope, gag, and pol Genes

Bernard Moss (NIAID), Patricia Earl (NIAID), Linda Wyatt (NIAID), Leigh Anne Steinmeyer (EM), Thomas VanCott (EM), Matthew Harris (EM) U.S. Provisional Application No. 60/459,175 filed 28 Mar 2003 (DHHS Reference No. E–023–2003/0–US–01); PCT Application filed 28 Mar 2004 (DHHS Reference No. E–023–2003/0–PCT–02)

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov.*

This invention claims Modified Vaccinia Ankara (MVA), a replication-deficient strain of vaccinia virus, expressing Human Immunodeficiency Virus (HIV) env, gag, and pol genes, where the genes are isolated from Ugandan Clade D isolates, Kenyan Clade A isolates, and Tanzanian Clade C isolates. In a rhesus macaque SHIV model, DNA priming followed by a recombinant MVA (rMVA) booster controlled a highly pathogenic immunodeficiency challenge. Both the DNA and the rMVA components of the vaccine expressed multiple immunodeficiency virus proteins. Two DNA inoculations at zero (0) and eight (8) weeks and a single rMVA booster at twenty-four (24) weeks effectively controlled an intrarectal challenge administered seven (7) months after the booster. Additionally, the inventors have generated data showing that inoculations of rMVA induce good immune responses even without DNA priming.

The inventors are continuing preclinical work on the vaccine, and have generated further data on the vaccine. Furthermore, the inventors are continuing to optimize the vaccine by genetically modifying the genes. This vaccine will be the subject of an upcoming Phase I clinical trial. These findings provide hope that a relatively simple multiprotein DNA/MVA vaccine can help to control the Acquired Immune Deficiency Syndrome (AIDS) epidemic.

Reagents to Produce Purified Human 14–3–3 Zeta and 14–3–3 Epsilon as Glutathione-S-Transferase Fusion Protein

David Klein, Surajit Ganguly (NICHD), DHHS Reference No. E–142–2002—Research Material.

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@mail.nih.gov*.

14–3–3 proteins are thought to be involved in some way in prion-based diseases, including Bovine Spongiform Encephalopathy (BSE). The preparations described in this invention can be used to make large amounts of two human forms of 14–3–3 proteins, zeta and epsilon. These proteins can be used to raise antisera against human 14–3–3 proteins and in assays of proteins that bind 14–3–3 proteins to monitor prion-caused diseases. Additionally, the 14–3–3 proteins described in this invention may be used as vaccines to immunize against proteins involved in prion diseases.

The materials described in this invention are available nonexclusively through a biological materials license. The materials are further described in Ganguly S. *et al.*, ''Role of a pineal cAMP-operated arylalkylamine N-acetyltransferase/14–3–3-binding switch in melatonin synthesis,'' *Proc. Natl. Acad. Sci.* U.S.A. 2001 Jul 3;98(14):8083–8 and Obsil T. *et al.*, ''Crystal structure of the 14–3–3zeta:serotonin N-acetyltransferase complex. a role for scaffolding in enzyme regulation,'' *Cell.* 2001 Apr 20;105(2):257–67.

Dated: April 18, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–9465 Filed 4–23–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

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 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 Eye Institute Special Emphasis Panel, Loan Repayment Program.

Date: April 29, 2004.

Time: 12 PM to 1:30 PM.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Houmam H Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892–9602, (301) 451–2020, *haraj@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 20, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–9458 Filed 4–23–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Health, Lung, and Blood Institute; 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, RFA-Research Scientist Award for Minority Institutions—(Not–HL–03–015).

Date: May 20, 2004.

Time: 7 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person Chitra Krishnamurti, PhD., Review Branch, Room 7206, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0303.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, RFA–HL–04–002, Partnership Programs to Reduce Cardiovascular Disparities.

Date: May 21, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person Chitra Krishnamurti, PhD., Review Branch, Room 7206, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0303.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233,, National Center for Sleep Disorders Research: 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 20, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–9454 Filed 4–23–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting.

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 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 Child Health and Human Development Special Emphasis Panel, Subplate Neurons in Survivors of Prematurity.

Date: April 29, 2004.

Time: 3 p.m. to 4:30 p.m.