comments should be received within 60 days of this notice.

Proposed Project: Mechanisms of Foodborne Infectious Disease Outbreaks—New—Epidemiology Program Office (EPO), Centers for Disease Control and Prevention (CDC).

This study will systematically determine how local and state health departments find out about disease outbreaks. While it is assumed that speed and accuracy of outbreak detection can be improved, there is little reported analysis of current detection methods at the state and local levels. Great attention is being focused on improving infectious disease outbreak detection in the United States (U.S.), heightened by concerns of U.S. vulnerability to bioterrorist attack, and the inclusion of the development of enhanced syndromic surveillance systems. This information can be used to identify ineffective successful methods, and to motivate investments in alternative methods for outbreak detection.

The investigation will consist of a collection of available documentation about the outbreak and administration of a questionnaire to the local or state health department representative who identified each of 250 different outbreaks, which are sampled from the Electronic Foodborne Outbreak Reporting System (EFORS) database. The questionnaire will consist of both closed- and open-ended items, and will be administered via Web-form or telephone interview. The initial 250 outbreak sample will be stratified by State, partly in order to reasonably distribute survey burden. With an anticipated 80% response rate, the final sample will be approximately 200 outbreaks (and respondents).

Additional efforts to reduce survey burden will include completion of as many of the questionnaire items as possible prior to administration (based on supporting documents), and Web-form or telephone administration options. There will be no cost to respondents.

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and Local Health Departments Representatives	200	1	1	200
Total				200

Dated: December 16, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–31524 Filed 12–22–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing, as required by the Federal Advisory Committee Act, that the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2003.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Committee Management Officer, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees through September 30, 2003:

Center for Biologics Evaluation and Research
- Biological Response Modifiers Advisory Committee
- Vaccines and Related Biological Products Advisory Committee

Center for Drug Evaluation and Research
- Anti-Infective Drugs Advisory Committee
- Arthritis Advisory Committee
- Cardiovascular and Renal Drug Advisory Committee
- Gastrointestinal Drug Advisory Committee

National Center for Toxicological Research
- Science Advisory Board to the National Center for Toxicological Research
- Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee)

Center for Devices and Radiological Health
- Medical Devices Advisory Committee (consisting of reports for the Circulatory System Devices Panel; Gastroenterology and Urology Devices Panel; General and Plastic Surgery Devices Panel; Dental Products Panel; Obstetrics and Gynecology Devices Panel; Neurological Devices Panel; Ophthalmic Devices Panel; Orthopaedic and Rehabilitation Devices Panel; Radiological Devices Panel)

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and

2. The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: December 15, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–31494 Filed 12–22–03; 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, DHHS.

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.

Methods and Compositions of Defensin-Antigen Fusion Proteins and Chemokine-Antigen Fusion Proteins as Vaccines for Tumors and Viral Infection

Arya Biragyn (NCI).

PCT Application No. PCT/US01/43830 filed 19 Nov 2001 (DHHS Reference No. E–024–2002/0–PCT–02).

Licensing Contact: Catherine Joyce; (301) 435–5031; *joycec@mail.nih.gov*.

This invention relates to the development of a vaccine for increasing the immunogenicity of a tumor antigen, thus useful for the treatment of cancer, as well as a vaccine for increasing the immunogenicity of a viral antigen, thus allowing treatment of viral infection. In particular, the present invention provides a fusion protein comprising a defensin or chemokine fused to either a tumor antigen or viral antigen which is administered as either a protein or nucleic acid vaccine to elicit an immune response effective in treating cancer or effective in treating or preventing viral infection. In particular, the C–C chemokine macrophage inflammatory protein (MIP–3α) was shown to be particularly effective in increasing the immunogenicity of a tumor antigen. Aspects of this work have been published as a PCT patent application with publication number WO 03/025002.

This technology is available for licensing on an exclusive or a non-exclusive basis.

Dated: December 16, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–31652 Filed 12–22–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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.

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Improved Endogenous Opioid Anti-Nociception With Reduced Neurodegeneration, Hyperalgesia, Allodynia and Tolerance

Amina Woods, Toni Shippenberg, and Lawrence Sharp (NIDA).

U.S. Provisional Application No. 60/459,830 filed 01 Apr 2003 (DHHS Reference No. E–276–2001/0–US–01).

Licensing Contact: Norbert Pontzer; (301) 435–5502; *pontzern@mail.nih.gov*.

Endogenous opioid peptides and receptors evolved to modulate nociceptive input in response to injury. One of those peptides, dynorphin, acts on the kappa opioid receptor subtype to produce analgesia without sedation, respiratory depression or constipation. Prior to this invention, dynorphin was not an acceptable analgesic because of certain severe toxic side effects, when given in doses higher than physiological concentrations, mainly NMDA mediated neurotoxicity. Dynorphin produces its deleterious side effects by producing an NMDA mediated motor paralysis. In disease states such as stroke, spinal cord injury or neuropathic pain, activation of NMDA receptors by endogenous dynorphin may lead to neurodegeneration, hyperalgesia and allodynia. Tolerance to opiate drugs may also be mediated by the NMDA actions of dynorphin. This invention provides materials and methods to block NMDA receptor activation by dynorphin thus allowing the use of exogenous dynorphin as a beneficial nociceptive agent without side effects and preventing pathological actions of endogenous dynorphin in response to injury. Experimental data demonstrate: (1) attenuation of motor activity deficits, flaccid paralysis and mechanical allodynia produced by dynorphin administration; (2) reduction of infarct size and locomotor deficits after cerebral ischemia; (3) the reduction of morphine tolerization; and (4) so far no visible side effects.

Pain Control by the Selective Local Ablation of Nociceptive Neurons

Michael Iadarola and Zoltan Olah (NIDCR).

PCT/US01/09425 filed 22 Mar 2001, published as WO 02/076444 (DHHS Reference No. E–109–2000/0–PCT–02).

Licensing Contact: Norbert Pontzer; (301) 435–5502; *np59n@nih.gov*.

The vanilloid receptor (VR) is a cation channel predominantly expressed on the peripheral processes and perikarya of nociceptive primary afferent neurons. Previous studies have shown that activation of the peripheral receptors by agonists such as capsaicin from hot peppers, or the much more potent resiniferatoxin, produces acute pain sensation which may be followed by desensitization. These inventors discovered that administration of VR agonists in the vicinity of neuronal cell bodies expressing the VR receptor can actually destroy those cells. To control pain and inflammatory disorders, the present invention provides methods and kits for the selective ablation of pain sensing neurons. For example, the intraganglionic administration of a VR agonist selectively ablates primary afferent nociceptive neurons without impairing other sensory modalities. This invention will greatly enhance the ability to control pain, inflammation and other conditions mediated by nociceptive neurons while sparing mental function and other sensations.

This research has been described, in part, in Olah et al., J. Biol. Chem., 276, pp. 11021–11030, 2001.