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.

Method of Detecting and Quantifying Contaminants in Heparin Preparations

Description of Technology: Heparin is a naturally occurring acidic carbohydrate produced commercially from extracts of animal tissues (such as bovine lung or porcine intestine) and is used in the treatment of a wide range of diseases in addition to their classic anticoagulant activity. Heparin is also used to coat many medical devices, such as catheters, syringes, stents and filters. Recently, certain lots of heparin were associated with serious side effects and adverse events. Recalls were issued in multiple countries and it became evident that there was an extensive problem with heparin manufacture.

Traditional tests may not be able to determine the presence of contaminant(s) without lyophilizing and concentrating each sample and may not be suitable for testing finished medical devices. Therefore, there is a demonstrated need to develop other assay methods for detecting contaminating oversulfated compounds of any source in heparin and heparin-derived products.

This technology relates to methods for detecting and/or quantifying oversulfated glycosaminoglycans based on inhibition of nucleic acid polymerases and resistance to enzymatic degradation. It also relates to the use of these methods to screen and quantify pharmaceutical preparations such as heparin preparations for oversulfated contaminants.

Potential Applications: Robust, simple and effective method for detecting and optionally quantifying oversulfated contaminants in heparin preparations.

Development Status: The method has been developed and qualified for sensitivity and identity, but full validation and commercialization have not been undertaken.

Inventor: Daniela Verthelyi et al. (FDA).

Publication: C Tami, M Puig, JC Reepmeyer, H Ye, DA D'Avignon, L Buhse, D Verthelyi. Inhibition of Taq polymerase as a method for screening heparin for oversulfated contaminants. Biomaterials 2008 Dec;29(36):4808–4814.

Patent Status: U.S. Provisional Application No. 61/095,562 filed 09 Sep 2008 (HHS Reference No. E–227–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@hhs.nih.gov.*

Collaborative Research Opportunity: The FDA, Division of Therapeutic Proteins, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this high throughput screening test for oversulfated glycosamineglycan contaminants in heparin. Please contact Daniela Verthelyi at *daniela.verthelyi@fda.hhs.gov* or Alice Welch at *alice.welch@fda.hhs.gov* for more information.

Immunogenic West Nile Virus-Like Particles

Description of Technology: Currently, no specific vaccine or therapy for West Nile Virus (WNV) is available for human use; a killed-virus vaccine and booster is in use for horses (efficacy not yet reported). Virus-like particles (VLPs) are an exciting new strategy, as it combines the safety of killed-virus and DNA-based vaccines with the potential for immunogenicity of live-attenuated virus. VLPs have been used in approved vaccine for humans, including human papilloma virus (HPV). Generating VLPs for West Nile Virus, however, has proven difficult.

The inventors have successfully generated West Nile VLPs in insect cells by using recombinant baculoviruses expressing the WNV structural proteins prME or CprME. Mice immunized with purified West Nile VLPs developed antibodies specific to WNV with potent neutralizing activities; moreover, the mice showed no morbidity or mortality after a subsequent challenge with live WNV and showed no evidence of viremia or viral RNA in the spleen or brain.

The patent application covers applications ranging from pharmaceutical/vaccine preparations for WNV–LPs to methods for making and using them.

Applications: Antiviral therapies, vaccines, and diagnostic kits based on West Nile VLPs.

Advantages:

- Demonstrated efficacy in mice.
- Noninfectious.
- Manufacture using insect cells is simple and inexpensive.
- Vaccines or therapeutics are a preferable means to control infection versus the current method (reduce mosquito populations using toxic pesticides).
- First successful generation of West Nile VLPs.

Development Status: Successful completion of proof-of-principle tests in mice.

Market: For the last few years, the CDC has reported between 2,000–3,000 human cases of WNV in the United States each year, typically with a mortality rate of about 5–6% (cumulatively since 1999, 27,000 cases and approaching 2,000 deaths). People over age 50 are at greatest risk for severe illness. Birds and horses are also vulnerable, with up to about 15,000 horse cases reported per year.

Inventors: T. Jake Liang (NIDDK) et al.

Relevant Publication: M Qiao et al. Induction of sterilizing immunity against West Nile Virus (WNV), by immunization with WNV-like particles produced in insect cells. J Infect Dis. 2004 Dec 15;190(12):2104–2108.

Patent Status: HHS Reference No. E–352–2003/0—U.S. Patent Application No. 11/579,459 (2008/0118528) and European Patent Application 05746277.2, both filed 03 Nov 2006 (from PCT publication WO 2005/018560) and claiming priority to 4 May 2004.

Licensing Status: Available for licensing.

Licensing Contact: Bruce Goldstein, J.D., M.S.; 301–435–5470; *goldsteb@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases, Liver Diseases Branch, is seeking parties

interested in collaborative research directed toward molecular strategies for vaccine and antiviral development, and animal models of viral hepatitis C. For more information, please contact Dr. T. Jake Liang at 301–496–1721, *jliang@nih.gov*, or Ms. Patricia Lake at 301–594–6762, *lakep@mail.nih.gov*.

Dated: April 29, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–10410 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Implementation of Post-Approval Studies for Medical Devices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Implementation of Post-Approval Studies for Medical Devices.'' The purpose of the workshop is to facilitate discussion among FDA and other interested parties on issues related to the implementation of Post-Approval Studies for medical devices.

Date and Time: The workshop will be held on June 4, 2009, from 9 a.m. to 5 p.m. and June 5, 2009, from 9 a.m. to 12 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 8 a.m., and registration will begin at 8:30 a.m. Please pre-register by May 28, 2009, using the instructions in this document.

Location: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Contact Persons: Ellen Pinnow, Center for Devices and Radiological Health (HFZ–541), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2373, e-mail: *ellen.pinnow@fda.hhs.gov*; or Daniel Canos, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2369, *daniel.canos@fda.hhs.gov*.

Registration: E-mail your name, title, organization affiliation, address, and e-mail contact information to Stephanie Zafonte at *SZafonte@s-3.com*. There is no fee to attend the workshop, but attendees must register in advance. The registration process will be handled by Social and Scientific Systems, which has extensive experience in planning, executing, and organizing educational meetings. Although the facility is spacious, registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

If you need special accommodations because of a disability, please contact Ellen Pinnow (see *Contact Persons*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on issues related to the conduct of Post-Approval Studies for medical devices.

II. What Are the Topics We Intend To Address at the Public Workshop?

We hope to discuss a large number of issues at the workshop, including, but not limited to:

- Regulatory requirements for implementing a Post-Approval Study for medical devices;
- Challenges and successful strategies for the recruitment of participants for Post-Approval Studies;
- Challenges and successful strategies for the retention and compliance with follow-up requirements of participants for Post-Approval Studies;
- Using existing infrastructure (e.g., national registries) to facilitate Post-Approval Studies; Using innovative strategies to facilitate Post-Approval Studies;
- Clinical research organizations, industry, academia, and other clinical trial consultant's perspectives on all of the previous issues related to implementing Post-Approval Studies for medical devices.

III. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html*.

Dated: April 29, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E9–10426 Filed 5–5–09; 8:45 am]

BILLING CODE 4160–01–S

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. 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Unsolicited Multi-Project Application.

Date: May 22, 2009.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call).

Contact Person: Peter R Jackson, Ph.D., Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700–B Rockledge Drive, MSC 7616 Room 2220, Bethesda, MD 20892–7616. 301–496–2550.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Ancillary Studies in Immunomodulation Clinical Trials.

Date: May 29, 2009.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Paul A. Amstad, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616. 301–402–7098. *pamstad@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10422 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P