Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9047, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5000.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: CGMP for Phase 1 Investigational Drugs'' dated July 2008. This guidance provides assistance in applying CGMP required under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)) in the manufacture of most investigational new drugs used in phase 1 clinical trials (phase 1 investigational drugs). The guidance is being issued concurrently with a final rule that specifies that the manufacture of most investigational new drugs manufactured for use in phase 1 clinical trials do not have to comply with the specific regulatory requirements in part 211 (21 CFR part 211).

Because a phase 1 clinical trial initially introduces an investigational new drug into human subjects, appropriate CGMP helps ensure subject safety. This guidance applies, as part of CGMP, quality control principles to the manufacture of phase 1 investigational drugs (i.e., interpreting and implementing CGMP consistent with good scientific methodology), which foster CGMP activities that are more appropriate for phase 1 clinical trials, improve the quality of phase 1 investigational drugs, and facilitate the initiation of investigational clinical trials in humans while continuing to protect trial subjects. For the manufacture of phase 1 investigational drugs described in this guidance (see section III of the guidance), this guidance will replace the guidance issued in 1991 (56 FR 7048, February 21, 1991) entitled ''Preparation of Investigational New Drug Products (Human and Animal)'' (the 1991 guidance). However, the 1991 guidance still applies to the manufacture of investigational new products (human and animal) used in phase 2 and phase 3 clinical trials.

In the **Federal Register** of January 17, 2006 (71 FR 2552), FDA announced the availability of the draft guidance entitled ''INDs—Approaches to Complying with CGMP During Phase 1'' dated January 2006. FDA received a moderate number of comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated January 2006.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance for part 211 have been approved under OMB control number 0910–0139.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: July 9, 2008.

Jeffrey Shuren,

Associate Comissioner for Policy and Planning.

[FR Doc. E8–16002 Filed 7–14–08; 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.

Neutralization of Hepatitis C Virus (HCV)

Description of Technology: Available for licensing and commercial development are anti-hepatitis C virus (HCV) vaccines, therapeutics and inhibitors. The invention is based on mapping studies conducted by the inventors of two epitopes within HCV E2: epitope I and epitope II. It has been discovered that epitope I is involved in virus neutralization but that epitope II mediates antibody interference; probably an adaptation of the virus to obfuscate the immune system. The present invention provides compositions and methods for treating and or preventing HCV infection caused by HCV. The invention is directed to a HCV E2 polypeptide substitution of

amino acids LFY of the skein LFY in epitope II. In certain embodiments, the invention is directed to a HCV E2 polypeptide deletion of amino acids LFY of the skein LFY in epitope II. In additional embodiments, the invention is directed to a HCV E2 polypeptide addition of amino acids between LFY of the skein LFY in epitope II. The above are directed to attenuating or disabling the interference effect of HCV-E2 epitope II.

In additional embodiments, the invention is directed to use of epitope II as a molecular decoyant. In further embodiments, the invention is directed to use of epitope II to affinity purify an immune globulin to deplete interfering antibodies from and enrich neutralizing antibodies in the preparation.

Applications: Antiviral; Hepatitis C Virus (HCV) therapy.

Inventors: Pei Zhang, Marian Major, Stephen Feinstone (FDA).

Publications:

1. P Zhang et al. Hepatitis C virus epitope-specific neutralizing antibodies in Igs prepared from human plasma. Proc Natl Acad Sci USA. 2007 May 15;104(20):8449–8454.

2. MY Yu et al. Neutralizing antibodies to hepatitis C virus (HCV) in immune globulins derived from anti-HCV-positive plasma. Proc Natl Acad Sci USA. 2004 May 18;101(20):7705–7710.

Patent Status: U.S. Provisional Application No. 61/002,031 filed 06 Nov 2007 (HHS Reference No. E–276–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301–435–5031; *tangrc@mail.nih.gov.*

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research, Laboratory of Plasma Derivatives, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Michelle Hawley at 301–827–1991 or *michelle.hawley@fda.hhs.gov* for more information.

Treatment of Skin Conditions Using DKK1

Description of Technology: This invention discloses a method for inducing non-palmoplantar skin (skin of the trunk, arms, and face etc.) to develop characteristics of palmoplantar skin (skin of the soles and palms). This effect is achieved by use of Dickkopf 1 (DKK1), a protein which is highly expressed by palmoplantar fibroblasts and is a known antagonist of the Wnt signaling pathway. Topical application of DKK1 to non-palmoplantar skin induces the development of increased skin thickness, decreased pigmentation, and decreased hair growth. These characteristics are desirable for treating several dermatological conditions.

The skin thickening caused by topical application of DKK1 can be useful for skin grafts, and skin ulcers or abrasions. Decreased skin pigmentation, experimentally achieved by either topical or in vitro application of DKK1, may be desirable for conditions such as uneven skin pigmentation, pigmented birthmarks, or post inflammatory pigmentation. Suppressed hair growth may be cosmetically desirable for some areas of the skin, and in conditions such hypertrichosis, adrenal hyperplasia, or polycystic ovarian syndrome. DKK1 treatment may also be important for treating or preventing certain melanomas which involve hyperplastic or pre-malignant lesions.

Applications: Useful for skin grafts, skin ulcers, skin abrasions, fragrance dermatitis, vitiligo, etc.; Treatment of several conditions which require decreased skin pigmentation; Decreased hair growth for cosmetic or therapeutic purposes.

Development Status: Early stage.

Inventors: Vincent J. Hearing et al. (NCI).

Publication: Y Yamaguchi, T Passeron, T Hoashi, H Watabe, F Rouzaud, K Yasumoto, T Hara, C Tohyama, I Katayama, T Miki, VJ Hearing. Dickkopf 1 (DKK1) regulates skin pigmentation and thickness by affecting Wnt/β-catenin signaling in keratinocytes. FASEB J. 2008 Apr;22(4):1009–1020.

Patent Status:

U.S. Provisional Application No. 60/873,874 filed 07 Dec 2006 (HHS Reference No. E–321–2006/0–US–01).

PCT Application No. PCT/US2007/086855 filed 07 Dec 2007 (HHS Reference No. E–321–2006/0–PCT–02).

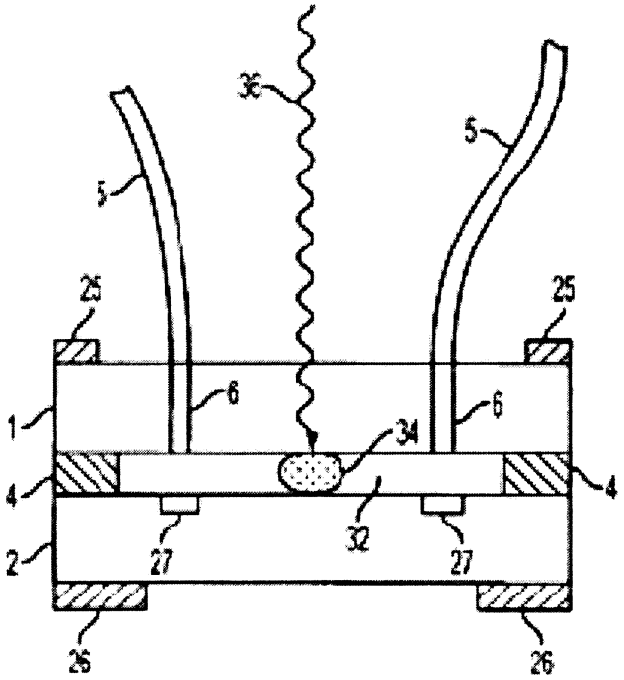
Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Jasbir (Jesse) S. Kindra, J.D., M.S.; 301–435–5170; *kindraj@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Cell Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of DKK1 or a bioactive fragment of DKK1 to treat abnormal pigmentation of the skin or to regulate hair growth. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Flow-Through Thermal-Expansion-Compensated Microcells for Analytical Transmission Infrared Spectroscopy

Description of Technology: Available for licensing and commercial distribution are optical cells spectroscopically stable and can be used for spectroscopic measurement in transmission, sample reflection, back plate reflection, emission, or scattering modes. The cell allows fluid in a sample space to be exchanged without separating a front or a back plate from a spacer, allows a solid sample to be placed in or removed from the sample space, requires only a small amount of sample, and allows for different sample gaps to be easily and inexpensively set. Alternatively, the spacers can be manufactured using a hydrocarbon-resistant polymer so that samples dissolved in organic solvents can be used without the risk of changing the spectral properties of the microcell and solvent leakage from the sample space. The inventive cell and methods allow spectral measurements to be taken over wavelengths ranging at least from the mid-infrared to the vacuum ultraviolet, provide a simple path for light traveling through a sample, and allow fast kinetic processes to be detected and monitored reproducibly and sensitively.



Applications: Analytics; Spectroscopy; Infrared spectroscopy; Chemical Imaging; Material characterization; Quality control; Chemometrics in chemical and pharmaceutical manufacturing; Forensic applications; Tissue pathology diagnostics

Inventors: Edward Mertz and James Sullivan (NICHD).

Publications:

1. Makareeva E, Mertz EL, Kuznetsova NV, Sutter MB, DeRidder AM, Cabral WA, Barnes AM, McBride DJ, Marini JC, Leikin S. Structural heterogeneity of type I collagen triple helix and its role in osteogenesis imperfecta. J Biol Chem. 2008 Feb 22;283(8):4787–4798.

2. Mertz EL, Leikin S. Interactions of inorganic phosphate and sulfate anions with collagen. Biochemistry. 2004 Nov 30;43(47):14901–14912.

Patent Status:

U.S. Patent 7,355,697 issued 08 Apr 2008 (HHS Reference No. E–096–2004/0–US–01).

International Patent Application No. PCT/US2005/030218 filed 25 Aug 2005, which published as WO 2006/026342 on 09 Mar 2006 (HHS Reference No. E–096–2004/0–PCT–02).

European Patent Application 05786373.9 filed 26 Aug 2005 (HHS Reference No. E–096–2004/0–EP–03).

U.S. Patent Application No. 11/826,806 filed 18 Jul 2007 (HHS Reference No. E–096–2004/1–US–01).

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

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The Eunice Kennedy Shriver National Institute of Child Health and Human Development, Section on Physical Biochemistry is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize microcells for infrared and other spectroscopies and their applications to pathology diagnostics. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Rapid and Sensitive Detection of Nucleic Acid Sequence Variations

Description of Technology: The ability to easily detect small mutations in nucleic acids, such as single base substitutions, can provide a powerful tool for use in cancer detection, perinatal screens for inherited diseases, and analysis of genetic polymorphisms such as genetic mapping or for identification purposes. Current approaches make use of the mismatch that occurs between complimentary strands of DNA when there is a genetic mutation, the electrophoretic mobility differences caused by small sequence changes, and chemicals or enzymes that can cleave heteroduplex sites. Some of these methods, however, prove to be too cumbersome, are unable to pinpoint mutations, only detect a subset of mutations, or involve the use of hazardous materials.

The current invention takes advantage of the ability of transposons, or mobile genetic elements, to move from one part of the genome to another by the cleavage and joining of their sequences into the target site; a reaction facilitated by a transposase enzyme. The phage Mu transposase is capable of inserting the right end sequence of the Mu transposon into any DNA sequence both *in vitro* and *in vivo.* The surprising discovery that the Mu transposase displays a strong preference for inserting Mu-end DNA into mismatched sites, the very sites which occur when DNA is mutated and paired with its complementary strand that does not have the corresponding mutation, makes it a powerful tool for detecting variations in nucleic acid sequences. In this system, the transposition of Mu-end DNA at a site is used to indicate the presence of a nucleic acid mismatch or mutation at that site. The invention can be used with labeled Mu-end DNA to further facilitate the precise mapping of the mutations. This specificity allows Mu to detect even single base mutations among a large quantity of non-specific DNA. The Mu detection system is simple, rapid, and highly sensitive compared to current methods and can find a broad range of use in genetic research and the diagnosis of several diseases such as cystic fibrosis, spinal and bulbar muscular dystrophy, human fragile-X syndrome, and Huntington's disease.

Applications:

Fast, simple screening for genetic mutations in several diseases such as cystic fibrosis, spinal and bulbar muscular dystrophy, human fragile-X syndrome, Huntington's disease,

detection of birth defects, and paternity testing, etc.

Genetic mapping and identification.

Development Status: Early stage.

Inventors: Katsuhiko Yanagihara and Kiyoshi Mizuuchi (NIDDK).

Publication: Yanagihara K and Mizuuchi K. Mismatch-targeted transposition of Mu: a new strategy to map genetic polymorphism. Proc Natl Acad Sci USA. 2002 Aug 20; 99(17):11317–11321.

Patent Status: U.S. Patent No. 7,316,903 issued 08 Jan 2008 (HHS Reference No. E–071–2003/0–US–02).

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

Licensing Contact: Jasbir (Jesse) S. Kindra, JD, MS; 301–435–5170; *kindraj@mail.nih.gov.*

Collaborative Research Opportunity: The Section on Genetic Mechanisms, LMB, NIDDK is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Mu transposition system as a tool for mutation detection and other genetic research/manipulation. Please contact Kiyoshi Mizuuchi at *kmizu@helix.nih.gov* for more information.

Dated: July 8, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–16134 Filed 7–14–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 Cancer Institute Initial Review Group; Subcommittee A—Cancer Centers.

Date: August 7–8, 2008.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Gail J. Bryant, MD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd, Room 8107, MSC 8328, Bethesda, MD 20892–8328, (301) 402–0801, *gb30t@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 9, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–16139 Filed 7–14–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

National Protection and Programs Directorate; Submission for Review: TRIPWire User Registration 1670–NEW

AGENCY: National Protection and Programs Directorate, Infrastructure Protection, DHS.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Department of Homeland Security (DHS) invites the general public and other federal agencies to comment on new information collection request 1670–NEW, TRIPWire User Registration. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), DHS is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until September 15, 2008. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to Department of Homeland Security, Attn: IP/PSCD/Charlie Payne, Mail Stop 8540, 245 Murray Lane, SW., Washington, DC 20528–8540, or e-mail *obp@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Department of Homeland Security, Attn: IP/PSCD/Charlie Payne, Mail Stop 8540, 245 Murray Lane, SW., Washington, DC 20528–8540, or e-mail *obp@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Infrastructure Protection.

Title: TRIPWire User Registration.

OMB Number: 1670–NEW.

Frequency: Once.

Affected Public: Federal, State, Local, Tribal.

Number of Respondents: 5000.

Estimated Time Per Respondent: 10 minutes.

Total Burden Hours: 834 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintaining): None.

Description: The Technical Resource for Incident Prevention (TRIPWire) is DHS's online, collaborative, information-sharing network for bomb squad, law enforcement, and other emergency services personnel to learn about current terrorist improvised explosive device (IED) tactics, techniques, and procedures, including design and emplacement considerations. Developed and maintained by the DHS Office for Bombing Prevention (OBP), the system combines expert analyses and reports with relevant documents, images, and videos gathered directly from terrorist sources to assist law enforcement to anticipate, identify, and prevent IED incidents. The TRIPWire portal contains sensitive information related to terrorist use of explosives and therefore user information is needed to verify eligibility and access to the system.