versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Potassium Citrate, 10 mEq/packet and 20 mEq/packet, is the subject of NDA 19–647, held by Nova-K LLC, and initially approved on October 13, 1988. Potassium Citrate is indicated for the management of renal tubular acidosis with calcium stones, hypocitraturic calcium oxalate nephrolithiasis of any etiology, and uric acid lithiasis with or without calcium stones.

Potassium Citrate, 10 mEq/packet and 20 mEq/packet, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Nomax, Inc., submitted a citizen petition dated April 18, 2013 (Docket No. FDA–2013–P–0503), under 21 CFR 10.30, requesting that the Agency determine whether Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Potassium Citrate, 10 mEq/packet and 20 mEq/packet, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Potassium Citrate, 10 mEq/packet and 20 mEq/packet, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Potassium Citrate, 10 mEq/packet and 20 mEq/packet, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Potassium Citrate, 10 mEq/packet and 20 mEq/packet, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24780 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, 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. 209 and 37 CFR Part 404 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.

FOR FURTHER INFORMATION CONTACT: 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.

Peptide Inhibitor of p38 Mapk Signaling for the Treatment of Inflammatory Autoimmune Diseases and Inflammatory Cancers

Description of Technology: This invention relates to a peptide fragment of GADD45A growth arrest and DNA-damage-inducible, alpha (Gadd45a), a protein involved in the p38 Map kinase signaling pathway. Although the fragment is only 15 amino acids in length, it retains the functionality of Gadd45a by inhibiting enzymatic activity of tyrosine-323-phosphorylaled p38 *in vitro.* The peptide fragment is tagged to render it cell-permeable and, according to *in vitro* studies, it exhibits minimal toxicity. The inventors have found that the fragment readily penetrates T cells to inhibit (a) proliferation in response to T cell receptor-mediated stimulation; (b) skewing of T cells to Th I and Th 17 cells; and (c) inflammatory cytokine production. As a result, this fragment has anti-inflammatory properties and has potential as a therapeutic for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Potential Commercial Applications: Treatment for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Competitive Advantages: Minimal cellular toxicity.

Development Stage: In vitro data available.

Inventors: Jonathan D. Ashwell, Mohammed S. Alam, Paul R. Mittelstadt (all of NCI).

Intellectual Property:

- HHS Reference No. E–281–2012/0—US Provisional Application No. 61/728,368 filed 20 Nov 2012.
- HHS Reference No. E–281–2012/1—US Provisional Application No. 61/774,066 filed 07 Mar 2013.

Licensing Contact: Jaime M. Greene; 301–435–5559; *greenejaime@mail.nih.gov*.

Cannabinoid Receptor 1 (CB1) Inverse Agonists for the Treatment of Diabetes, Obesity and Their Complications

Description of Technology: Endocannabinoids are lipid signaling molecules that act on the same cannabinoid receptors—CB1 and CB2—that recognize and mediate the effects of marijuana. Activation of CB1 receptors increases appetite and the biosynthesis and storage of lipids, inhibits the actions of insulin and leptin, and promotes tissue inflammation and fibrosis. This has led to the development of CB1 receptor blocking drugs (inverse agonists) for the treatment of obesity and its metabolic complications, referred to as the metabolic syndrome. However, many CB1 inverse agonists can cross the blood-brain barrier, causing psychiatric side effects.

Researchers at NIH have now developed a novel strategy to structurally modify CB1 inverse agonists with the goals of (1) limiting their brain penetrance without losing their metabolic efficacy due to CB1 inverse agonism, and (2) generating compounds whose primary metabolite directly targets enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. These modified CB1 inverse agonists can be used to effectively treat metabolic syndrome and its complications without the risk of the psychiatric side effects, and have improved antiinflammatory and antifibrotic efficacy due to acting on more than one molecular target.

Potential Commercial Applications:

- Treatment for obesity
- Treatment for metabolic syndrome
- Treatment of diabetes
- Treatment of fibrosis

Competitive Advantages:

- Inhibits metabolic activity without causing psychiatric side effects
- Offers improved antiinflammatory and antifibrotic efficacy

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: George Kunos (NIAAA), Milliga Iyer (NIAAA), Resat Cinar (NIAAA), Kenner Rice (NIDA)

Intellectual Property: HHS Reference No. E–282–2012/0—US Provisional Application No. 61/725,949 filed 11 Nov 2012.

Licensing Contact: Jaime M. Greene; 301–435–5559; *greenejaime@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute on Alcohol Abuse and Alcoholism, Laboratory of Physiologic Studies, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize peripherally restricted CB1 receptor blockers with improved efficacy. For collaboration opportunities, please contact George Kunos, M.D., Ph.D. at *George.Kunos@nih.gov* or 301–443–2069.

Software Method for 2–D NMR Tissue Compartment Analysis

Description of Technology: The invention pertains to a method for improving the accuracy of compartment characterization using NMR. Conventional methods use Laplace transformation analyzed one dimensional transverse NMR relaxometry to investigate spin-lattice decay of water in diverse body compartments using. This method, although used extensively, is inaccurate and limited by signal-to-noise obscurities and when the materials and compartments to be analyzed vary in size or have disparate relaxation characteristics.

The improved method of this invention utilizes the detection of a 2-dimensional (2–D) NMR signal, created through use of a standard pulse sequence and variations, analysis of the signal using inverse Laplace transform, followed by projection of the resultant 2–D data onto a single axis corresponding to the parameter of original interest. The method can be extended to analyses for 3–D or higher dimensional experiments and inverse Laplace transforms.

Potential Commercial Applications:

- Compartment analysis
- Petroleum discovery
- Multiple sclerosis

Competitive Advantages:

Compartment resolution

Development Stage: Prototype

Inventors: Richard G. Spencer and Hasan Celik (NIA)

Intellectual Property: HHS Reference No. E–734–2013/0—Software. Patent protection is not being pursued for this technology.

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

Dated: October 18, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–24819 Filed 10–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a stakeholder meeting hosted by the NIH Scientific Management Review Board (SMRB). Presentations and discussions will address the optimal approaches to assessing the value of biomedical research supported by the NIH and will include input from stakeholders in biomedical research.

The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the SMRB is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board (SMRB).

Date: October 24–25, 2013.

Time: 9 a.m. on October 24, 2013 to 12:30 p.m. on October 25, 2013.

Agenda: Presentations and discussions will include: 1) an update from the SMRB's Working Group on Approaches to Assess the Value of Biomedical Research Supported by NIH, and 2) presentations that explore approaches to assess the value of biomedical research supported by NIH. Time will be allotted on the agenda for public comment. Sign up for public comments will begin approximately at 7:30 a.m. on October 24, 2013, and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement