Customs and Border Protection's (CBP's) staff on enforcement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States.

DATES: Submit written or electronic comments concerning the CPG at any time.

ADDRESSES: Submit written comments on the CPG 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 7, 2008 (73 FR 66411), FDA announced the availability of a draft CPG entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' After considering the one comment received, FDA revised the CPG, with CBP concurrence, where appropriate. The revised CPG provides written guidance to FDA's and CBP's staff on enforcement of section 307 of the Bioterrorism Act and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States.

FDA is issuing this CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents the agency's current thinking on its enforcement policy concerning prior notice. 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. Comments

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

III. Electronic Access

An electronic version of the CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: April 29, 2009.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. E9–10556 Filed 5–4–09; 4:15 pm]

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.

Small Molecule Activators of Human Pyruvate Kinase for Treatment of Cancer and Enzyme-Deficient Hemolytic Anemia

Description of Technology: NIH investigators have discovered a series of small compounds with the potential to treat a variety of cancers as well as hemolytic anemia. Contrary to most cancer medications, these molecules can be non-toxic to normal cells because they target a protein specific to the metabolic pathways in tumors, thus representing a significant clinical advantage over less-specific chemotherapeutics.

The invention described here is a series of small molecules that activate pyruvate kinase (PK) isoform M2. PK–M2 is a critical metabolic enzyme that is affected in all forms of cancer. Inactivation of PK–M2 leads to a buildup of metabolic intermediates inside the cell. Tumor cells require a buildup of metabolic intermediates in order to undergo rapid cell growth and proliferation. Hence, activation of PK–M2 in tumor cells may prevent the buildup of metabolic intermediates and thereby stall tumor cell proliferation or destroy the tumor cells. Further, while in normal adult cells only PK isoforms R, L, or M1 are active, in all tumors only PK–M2 is active. Therefore, PK–M2 activation would affect only tumor cells, and small-molecule PK–M2 activators are not expected to be toxic to healthy cells.

In addition, in patients with PK–R deficiency the buildup of metabolic intermediates in red blood cells ultimately leads to the loss of water from the cells and cell death. Small-molecule induced activation of PK–R in PK-deficient red blood cells may enhance vitality of these cells and decrease or eliminate enzyme-deficient hemolytic anemia in a patient.

Applications: Therapeutic for cancer; Therapeutic for enzyme-deficient hemolytic anemia.

Development Status: Early stage.

Market: In the United States in 2008, approximately 1.4 million people were diagnosed with cancer. In addition, approximately 12,000 people in the United States are chronically affected by PK-deficient hemolytic anemia.

Inventors: Craig J. Thomas et al. (NHGRI).

Publications: In preparation.

Patent Status: U.S. Provisional Application No. 61/104,091 filed 09 Oct 2008 (HHS Reference No. E–326–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*

Collaborative Research Opportunity: The NIH Chemical Genomics Center is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize appropriate lead compounds described in U.S. Provisional Application No. 61/199,763. Please contact Dr. Craig J. Thomas via e-mail (*craigt@nhgri.nih.gov*) for more information.

Polyclonal Antibodies to the Kidney Protein Sodium-Hydrogen Exchanger 3 (NHE3)

Description of Technology: Antibodies to NHE3, useful for immunoblotting and immunocytochemistry, are available to resell for research purposes. NHE3 is a membrane Na+/H+ exchanger involved in maintenance of fluid volume homeostasis in the kidney. It is expressed on the apical membrane of the renal proximal tubule and plays a major role in NaCl and HCO_3 absorption. The inventor has developed rabbit polyclonal antibodies directed against a peptide sequence common to human, rat and mouse NHE3.

Applications: Western blotting and immunocytochemistry.

Inventor: Mark A. Knepper (NHLBI).

Related Publication: Unpublished.

Patent Status: HHS Reference No. E–253–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov*.

Polyclonal Antibodies to Thiazide-Sensitive Sodium-Chloride Cotransporter (NCC)

Description of Technology: Antibodies to thiazide-sensitive sodium-chloride cotransporter (NCC), useful for immunoblotting and immunocytochemistry, are available to resell for research purposes. NCC is found on the apical membrane of the distal convoluted tubule, where it is the principal mediator of Na+ and CI reabsorption in this segment of the nephron. NCC is the target of thiazide diuretics used in the treatment of hypertension. The inventors have developed rabbit polyclonal antibodies directed against a peptide sequence in the C-terminal region of NCC.

Applications: Western blotting and immunohistochemistry.

Inventor: Mark A. Knepper (NHLBI).

Related Publication: HL Biner, MP Arpin-Bott, J Loffing, X Wang, M Knepper, SC Hebert, B Kaissling. Human cortical distal nephron: distribution of electrolyte and water transport pathways. J Am Soc Nephrol. 2002 Apr;13(4):836–847.

Patent Status: HHS Reference No. E–254–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov*.

Polyclonal Antibodies to NKCC2, a Kidney-Specific Member of the Cation Chloride Co-transporter Family, SLC12A1

Description of Technology: Antibodies to NKCC2, useful for immunoblotting and immunocytochemistry, are available to resell for research purposes. NKCC2 is found on the apical surface of the thick ascending limb of the loop of Henle, where it facilitates transport of sodium, potassium, and chloride ions from the lumen of the renal thick ascending limb into the cell. Transport of sodium dilutes the luminal fluid, decreasing its osmolality creating an osmotic driving force for water reabsorption in the connecting tubule and cortical collecting duct under the influence of the hormone vasopressin. NKCC2 is blocked by loop diuretics such as furosemide. The inventor has developed rabbit polyclonal antibodies directed against a peptide sequence in the N-terminal tail of NKCC2.

Applications: Western blotting and immunocytochemistry.

Inventor: Mark A. Knepper (NHLBI).

Related Publications:

1. GH Kim, CA Ecelbarger, C Mitchell, RK Packer, JB Wade, MA Knepper. Vasopressin increases Na-K–2CI cotransporter expression in thick ascending limb of Henle's loop. Am J Physiol. 1999 Jan;276(1 Pt 2):F96–F103.

2. HL Brooks, AJ Allred, KT Beutler, TM Cofiman, MA Knepper. Targeted proteomic profiling of renal Na+ transporter and channel abundances in angiotensin II type 1a receptor knockout mice. Hypertension. 2002 Feb;39(2 Pt 2):470–473.

Patent Status: HHS Reference No. E–255–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov*.

Polyclonal Antibodies to the Kidney Protein Urea Transporter 1 (UTA1)

Description of Technology: Antibodies to UTA1, useful for immunoblotting and immunocytochemistry, are available to resell for research purposes. Urea Transporter 1 (UTA1) is activated by vasopressin and is responsible for urea transport across the apical membrane into the intracellular space within the renal inner medullary collecting duct. The inventor has developed rabbit polyclonal antibodies directed against a peptide sequence in human UTA1. Antibody also recognizes UTA3, another product of the same gene.

Applications: Western blotting and immunocytochemistry.

Inventor: Mark A. Knepper (NHLBI).

Related Publication: S Nielsen, J Terris, CP Smith, MA Hediger, CA Ecelbarger, MA Knepper. Cellular and subcellular localization of the vasopressin-regulated urea transporter in rat kidney. Proc Natl Acad Sci USA. 1996 May 28;93(11):5495–500.

Patent Status: HHS Reference No. E–268–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301–435–4074; *sstand@od.nih.gov*.

Dated: April 28, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–10452 Filed 5–5–09; 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, 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