in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately 2 exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

In the **Federal Register** of August 17, 2012 (77 FR 49818), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 201.25(d)	2	1	2	24	48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11630 Filed 5–15–13; 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. 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.

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.

A Diagnostic Kit for Assessing Exposure or Infection by the Koala Family of Retroviruses

Description of Technology: Inventors at the NIH have discovered a new family of infectious koala retroviruses that are correlated with the development of malignant neoplasias, including lymphomas and leukemias. This invention relates to a diagnostic kit for assessing exposure or infection by a koala retrovirus. The kit consists of specific primers and probes for the detection of three distinct subtypes of infectious koala retrovirus and may be useful in various species, including humans, primates, and koalas. Infectious koala retroviruses have been shown to infect human cells in culture, though the health implications in humans have not yet been fully determined.

Potential Commercial Applications:

- A diagnostic kit for assessing exposure or infection by the koala family of retroviruses
- May be useful in monitoring effectiveness of antiretroviral treatment

Competitive Advantages: Detection of newly discovered subtypes of infectious koala retroviruses.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Maribeth V. Eiden (NIMH), Wenqin Xu (NIMH), William M. Switzer (CDC), HaoQiang Zheng (CDC)

Intellectual Property: HHS Reference No. E–053–2013/0—US Application No. 61/784,763 filed 14 Mar 2013

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Mental Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize A Diagnostic Kit for Assessing Exposure or Infection by the Koala Family of Retroviruses. For collaboration opportunities, please contact Suzanne L. Winfield, Ph.D. at *winfiels@mail.nih.gov* or 301–402–4324.

Retroviral Vector Packaging Cell Lines and Purification Methods for Gene Therapy

Description of Technology: This invention relates to a novel gammaretroviral vector packaging cell line and method of producing gammaretroviral vectors suitable for gene therapy. The described vectors may contain the gibbon ape leukemia virus (GALV) envelope with a CD11D8 epitope tag enabling their purification on a monoclonal antibody conjugated column. These vectors have several advantages over existing systems, including a broader host range, higher infectivity, and lower potential for replication. Further, purification of retroviral vector particles via an epitope tag may remove cellular components and debris toxic to target cells and tissues, providing a safer method of delivery for patients receiving gene therapy.

Potential Commercial Applications: Retroviral vector particles for gene therapy.

Competitive Advantages:

- Broader host range
- Higher infectivity
- Lower potential for replication
- Decreased toxicity after purification

Development Stage:

- Early-stage
- In vitro data available

Inventors: Maribeth V. Eiden and Wenqin Xu (NIMH)

Intellectual Property: HHS Reference No. E–036–2013/0—US Application No. 61/759,516 filed 01 Feb 2013

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Mental Health is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize

Retroviral Vector Packaging Cell Lines and Purification Methods for Gene Therapy. For collaboration opportunities, please contact Suzanne L. Winfield, Ph.D. at *winfiels@mail.nih.gov* or 301–402–4324.

Enhanced Cancer Immunotherapy Using microRNA–155

Description of Technology: Tumor immunotherapy is a promising approach for the treatment of cancer. However, current T cell-based immunotherapies are limited by the poor engraftment and functionality of the transferred T cells. Moreover, lymphodepleting regimens used to enhance engraftment and function of transferred tumor-reactive T cells are plagued by life-threatening side effects.

The scientist at the NIH recently discovered that the overexpression of microRNA–155 (miR–155) in tumor-reactive murine CD8+ T cells can enhance T cell proliferation and anti-tumor efficacy without lymphodepletion and exogenous cytokine administration. Consequently, using the miR155 overexpressing human CD8+ T cells could provide a safer, more effective T cell-based immunotherapy. This invention describes miR155 CD8+ T cell compositions and methods of using the miR155 CD8+ T cells to treat cancer through adoptive immunotherapy.

Potential Commercial Applications: Use in enhanced adoptive immunotherapy to treat cancer.

Competitive Advantages:

- T cells with enhanced proliferation, survival, and function.
- Robust tumor response without the need of lymphodepletion and exogenous cytokine support.

Development Stage:

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

Inventors: Yun Ji, Luca Gattinoni, Nicholas Restifo (NCI)

Publication: Dudda JC, et al. MicroRNA–155 Is Required for Effector CD8(+) T Cell Responses to Virus Infection and Cancer. Immunity. 2013 Apr 18;38(4):742–53. [PMID 23601686]

Intellectual Property: HHS Reference No. E–272–2012/0—US Provisional Application No. 61/716,653 filed 22 Oct 2012

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the use of microRNA–155 to enhance T cell-based immunotherapies. For collaboration opportunities, please contact Luca Gattinoni at *gattinol@mail.nih.gov* or 301–451–6914, or Nicholas Restifo at *restifo@nih.gov* or 301–496–4904.

Pyruvate Kinase M2 Activators for the Treatment of Cancer

Description of Technology: This technology describes a series of small-molecule activators of the pyruvate kinase M2 isoform (PK–M2).

Pyruvate kinase (PK) is a critical metabolic enzyme that catalyzes the last step of the glycolytic pathway. It exists in several isoforms with different patterns of tissue expression. One isoform, PK–M2, is expressed in cells with a high rate of nucleic acid synthesis, including most tumors, which makes this enzyme an attractive target for cancer therapy. PK–M2 can occur in either a tetrameric form or a dimeric form in proliferating cells; a high tetramer to dimer ratio leads to energy production, while a low ratio channels metabolites into synthetic processes. In tumor cells, oncoproteins induce dimerization of PK–M2, resulting in the inactive form of the protein and allowing synthesis of building blocks for cell proliferation. Activation of PK–M2 in these cells may prevent the buildup of metabolic intermediates and thereby stall tumor cell proliferation. Further, after embryonic development PK–M2 expression is primarily restricted to tumor cells, so specific activators of PK–M2 would be expected to affect only tumor cells, and would be less likely to be toxic in normal tissues.

Investigators at the National Center for Advancing Translational Sciences have discovered a series of small molecules that specifically activate the PK–M2 isoform and that may be useful for the treatment of cancer. These compounds are based upon a substituted thieno[3,2-b]pyrrole[3,2-d]pyridazinone scaffold.

Potential Commercial Applications: Targeted therapeutic agent for cancer and other cell proliferation disorders.

Competitive Advantages:

- Compounds are specific to one isoform of pyruvate kinase.
- Compounds target tumor cells and not normal cells, so side effects may be reduced.
- Compounds are small molecules which may be further optimized.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Craig J. Thomas, Jian-Kang Jiang, Matthew B. Boxer, Min Shen, Douglas S. Auld (NCATS)

Publications:

1. Anastasiou D, et al. Pyruvate kinase M2 activators promote tetramer formation and suppress tumorigenesis. Nat Chem Biol. 2012 Oct;8(10):839–47. [PMID 22922757]

2. Anastasiou D, et al. Inhibition of pyruvate kinase M2 by reactive oxygen species contributes to cellular antioxidant responses. Science. 2011 Dec 2;334(6060):1278–83. [PMID 22052977]

3. Jiang J, et al. Evaluation of thieno[3,2-b]pyrrole[3,2-d]pyridazinones as activators of the tumor cell specific M2 isoform of pyruvate kinase. Bioorg Med Chem Lett. 2010 Jun 1;20(11):3387–93. [PMID 20451379]

Intellectual Property: HHS Reference No. E–298–2011/1—US Provisional Application No. 61/752,698 filed 15 Jan 2013

Related Technologies:

HHS Reference No. E–326–2008/0—

- US Patent Application No. 13/123,297 filed 25 Apr 2011
- US Patent Application No. 13/433,656 filed 29 Mar 2012
- Various international patent applications filed

HHS Reference No. E–120–2010/0—

- US Patent Application No. 13/643,594 filed 26 Oct 2012
- Various international patent applications filed

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences (NCATS) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Pyruvate Kinase M2 Activators for the Treatment of Cancer. For collaboration opportunities, please contact the Office of Strategic Alliances at *NCATSPartnerships@mail.nih.gov.*

Dated: May 10, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–11602 Filed 5–15–13; 8:45 am]

BILLING CODE 4140–01–P

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