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#### IV. 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 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

In addition, FDA concludes that the labeling statements in the guidance do not constitute a “collection of information” under the Paperwork Reduction Act. Rather, the labeling statements are “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.” (5 CFR 1320.3(c)(2)).

#### V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Center for Devices and Radiological Health, Safety Communications Page, “Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy,” (<http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm393576.htm>).
2. Public meeting in 2014, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, **Federal Register** notice, available at <http://www.gpo.gov/fdsys/pkg/FR-2014-06-09/pdf/2014-13290.pdf>.

Dated: November 19, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014–27857 Filed 11–24–14; 8:45 am]

**BILLING CODE 4164–01–P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request; The Genetic Testing Registry

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Sarah Carr, Acting Director, Office of Clinical Research and Bioethics Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 496–9838, or Email your request, including your address to: [OCRBP-OSP@od.nih.gov](mailto:OCRBP-OSP@od.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection:* The Genetic Testing Registry, 0925–0651, Expiration Date 02/28/2015—EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* Clinical laboratory tests are available for more than 5,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,536.

## ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Estimated annual number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Laboratory Personnel Using Bulk Submission .....	Minimal Fields .....	190	29	18/60	1,653
	Optional Fields .....	159	29	14/60	1,076
Laboratory Personnel Not Using Bulk Submission.	Minimal Fields .....	116	29	30/60	1,682
	Optional Fields .....	97	29	24/60	1,125

Dated: November 17, 2014.

**Lawrence A. Tabak,**  
Principal Deputy Director, National Institutes of Health.

[FR Doc. 2014-27898 Filed 11-24-14; 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, 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.

**SUPPLEMENTARY INFORMATION:** Technology descriptions follow.

#### T-cell Chimeric Receptors of TSLPR for Diagnosis and Immunotherapy of Cancer

Description of Technology: T-cell-based immunotherapies allow a patient's immune system to concentrate its efforts and destroy cancer cells. In the present technology, the researchers

at the National Cancer Institute have developed chimeric antigen receptors (or CARs), which encode an antigen binding domain specific for thymic stromal lymphopoietin receptor (TSLPR) and a T-cell signaling domain. TSLPR is over-expressed on the surface of approximately 10% of adult and pediatric B-cell precursor acute lymphoblastic leukemias (BCP-ALL).

Available for licensing is the above-reference CAR technology as well as methods for diagnosing and treating cancer using these CARs.

Potential Commercial Applications:

- Immunotherapy against cancer, especially leukemia
- Immunotoxins

Competitive Advantages: CAR receptors are specific for TSLPR. Development Stage:

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

Inventors: Terry Fry and Haiying Qin (NCI).

Publication: Qin H, et al. Pre-clinical development of a novel chimerical antigen receptor targeting high-risk pediatric ALL over-expressing Tslpr. Blood 2013 Nov 15;122(21):2665.

Intellectual Property:

- HHS Reference No. E-008-2014/0—US Provisional Application No. 61/912,948 filed 06 Dec 2013
- HHS Reference No. E-008-2014/1—US Provisional Application No. 61/991,697 filed 12 May 2014
- HHS Reference No. E-008-2014/2—PCT Application No. PCT/US2014/063096 filed 30 Oct 2014

Licensing Contact: Patrick McCue, Ph.D.; 301-435-5560; [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov)

#### Novel Bridged Bicyclic Thiazepinone Compounds

Description of Technology: The invention is directed to small molecules containing a novel, bridged, bicyclic thiazepinone pharmacophore. Invention compounds inhibit the Nav1.7 sodium channel. Additionally, invention compounds bind the human norepinephrine transporter (NET), with

selectivity over the serotonin transporter (SERT) and dopamine transporter (DAT).

Invention compounds could be used to treat neuropathic pain associated with diabetes and fibromyalgia, Attention Deficit Hyperactivity Disorder (ADHD), urinary incontinence, depression, anxiety, and other mood disorders.

Invention compounds can be conjugated with fluorescent or radioactive tags, and used to probe the structure and activity of the Nav1.7 sodium channel and NET.

Potential Commercial Applications:

- Therapeutic
- Chemical probe

Competitive Advantages:

- Small molecule compounds made using facile synthesis scheme
- Inhibition of Nav1.7 sodium channel
- NET inhibition with selectivity over other transporters

Development Stage:

- Early-stage
- In vitro data available

Inventors: Hans F. Luecke (NIDDK), Michael T. Scerba (NIDDK), Dongwook Kang (Daegu Catholic University).

Intellectual Property: HHS Reference No. E-224-2012/0—

- US Application No. 61/876,262 filed 09 Sept 2013
- PCT Application No. PCT/US2014/054660 filed 09 Sept 2014

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301-435-4074; [nguyenantczakla@mail.nih.gov](mailto:nguyenantczakla@mail.nih.gov).

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize use of bridged bicyclic thiazepinones. For collaboration opportunities, please contact Marguerite J. Miller, M.B.A. at [marguerite.miller@nih.gov](mailto:marguerite.miller@nih.gov) or 301-496-9003.