

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–4866 for the “Pediatric Post-Marketing Pharmacovigilance and Drug Utilization Reviews” that have been posted on FDA’s Web site between March 11, 2017, and September 12, 2017, but not presented at the September 12, 2017, PAC meeting. Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenneth Quinto, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5145, Silver Spring, MD 20993, 240–402–2221, email: kenneth.quinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation’s food supply, cosmetics, and products that emit radiation.

FDA is establishing a public docket, Docket No. FDA–2017–N–4866, to receive input on pediatric post-marketing pharmacovigilance and drug utilization reviews posted between March 11, 2017, and September 12, 2017, available on FDA’s Web site at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm>, but not presented at the September 12, 2017, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2017–N–4866. The docket will open on October 9, 2017, and remain open until October 20, 2017. These pediatric post-marketing pharmacovigilance and drug utilization reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. GRASTEK (Timothy Grass Pollen Allergen Extract) Tablet for Sublingual Use
2. ORALAIR (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Tablet for Sublingual Use

Center for Drug Evaluation and Research

1. ALOXI (palonosetron hydrochloride)
2. ARNUITY ELLIPTA (fluticasone furoate)
3. ASMANEX HFA and ASMANEX TWISTHALER (mometasone furoate inhalation)
4. CYMBALTA (duloxetine)

5. EMSAM (selegiline transdermal system)
6. LATISSE (bimatoprost ophthalmic solution) 0.03%
7. NAMENDA (memantine hydrochloride) and NAMENDA XR (memantine hydrochloride) extended-release
8. PRIFTIN (rifapentine)
9. REYATAZ (atazanavir)
10. TACLONEX (betamethasone dipropionate/calcipotriene hydrate) Topical Suspension 0.064%/0.005% and TACLONEX (betamethasone dipropionate/calcipotriene hydrate) Topical Ointment 0.064%/0.005%
11. ZETONNA (ciclesonide)

Dated: August 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18690 Filed 9–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to Nanobernetics, LLC (“Nanobernetics”) located in Maryland. **DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before September 20, 2017 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Jaime M. Greene, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, Rm. 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240)-276–5530;

Facsimile: (240)-276-5504 Email: greenejaine@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

EP Patent 1999277 (Application No. 07753436.0) filed 19 March 2007, titled "Apparatus for biosensor microarrays based on carbon nanotube transistors having biological probe materials, method for its production and method of electronically detecting a biological target material", validated in FR, DE, IE, and GB, HHS Reference No.: E-056-2007/0-EP-04;

Australia Patent 2007227415 (Application No. 2007227415) filed 10/16/08, titled "Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors", HHS Reference No.: E-056-2007/0-AU-05;

Canada Patent 2646465 (Application No. 2646465) filed 03/19/07, titled "Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors", HHS Reference No.: E-056-2007/0-CA-06;

Japan Patent 5048752 (Application No. 2009-501490) filed 03/19/07, titled "Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors", HHS Reference No.: E-056-2007/0-JP-07;

EP Patent 2570490 (Application No. 12160369.0) filed 03/19/07, titled "Apparatus for microarray binding sensors having biological probe materials using carbon nanotube transistors", validated in FR, DE, and GB. HHS Reference No.: E-056-2007/0-EP-08;

U.S. Patent 8,017,938 (Application No. 11/723,369), filed 19 March 2007, titled "Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors", HHS Ref. No.: E-056-2007/0-US-03; and

PCT Application No. PCT/US2007/06809, filed 19 March 2007, now abandoned, titled "Apparatus for Microarray Binding Sensors Having Biological Probe Materials Using Carbon Nanotube Transistors", HHS Ref. No.: E-056-2007/0-PCT-02.

U.S. Provisional Patent Application No. 60/743,524, filed 17 March 2006, now abandoned, titled "Apparatus for Microarray DNA Binding Sensors Using Carbon Nanotube Transistors", HHS Ref. No.: E-056-2007/0-US-01.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: "The development of an FDA-approved or cleared *in vitro* diagnostic for the detection of hematological malignancies, wherein nucleic acids encoding one or more of the following genes are detected: (1) BCR-ABL, (2) FLT3, (3) Btk, (4) Alk, (5) Bcl-2, (6) Akt, and (7) PI3K."

This technology discloses a microarray apparatus that uses carbon

nanotubes transistors and electronic circuitry to quantitatively measure changes in gene expression levels. Typically, microarrays are microscope glass slides spotted with thousands of different genes. The array does not have built-in reader, and the detection is performed using a fluorescence scanner after hybridization with fluorescently-tagged target DNA. For simple nucleic acid detection, current methods rely upon various combinations of enzymatic amplification of nucleic acids and fluorescent labeling of targets, which entail enzymatic manipulation of the nucleic acid being tested and chemical labeling, respectively. These methods are both time consuming and afford limited sensitivity. In cases where microarray technology is used as a tool for monitoring gene expression patterns and profiling of micro RNA (miRNA) in normal and cancerous tissue, quantification of changes has typically been optically-based. While this technique is highly sensitive, use of optical methods impedes progress in both system miniaturization and in direct interfacing with data collection electronics.

To overcome the limitation of current microarray technologies, the inventors have developed a highly sensitive microarray apparatus that uses carbon nanotube transistors for the electronic detection of biological probe-target binding. The present invention provides an apparatus for biological target material detection which uses an array of carbon nanotube transistors, with each being operated as a field effect transistor. A single carbon nanotube transistor is associated with a distinct biological probe material. The current versus voltage characteristics or transconductance between the source and drain electrodes is measured before and after a binding event between the biological probe and target materials. By using a mathematical relationship, the exact amount of target binding can be extracted. Importantly, the present apparatus offers a significant advantage in simplicity of protocol as the method used therewith does not require chemical or enzymatic manipulation of the target being detected.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Commercialization Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: August 25, 2017.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

[FR Doc. 2017-18668 Filed 9-1-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NCI Cancer Genetics Services Directory Web-Based Application and Update Mailer (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Margaret Beckwith, Office of Cancer Content, Office of Communications and Public Liaison (OCPL), 9609 Medical Center Drive, Rockville, MD 20892 or call non-toll-free number 240-276-6600 or email your request, including your address to: nciocpl@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written