of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

In the **Federal Register** of March 26, 2008 (73 FR 16018), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	2	1	2	4,500	9,000
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260	1	1	1	650	650
Total					12,854

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

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years.

Dated: June 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14258 Filed 6–23–08; 8:45 am]

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.

Novel Fluorinated Dmt-Tic Analogues for Use as PET Radiotracers

Description of Technology: Researchers at the NIH have developed fluorine-18 (^{18}F) labeled analogues specific for the delta-opioid receptors. These radioligands include analogues of the Dmt-Tic pharmacophore, containing a delta-opioid receptor antagonist that may be useful for imaging opioid receptors expressed in lung malignant tumors or other peripheral tumors that express delta-opioid receptors. This methodology might be readily applicable to Dmt-Tic pharmacophoric ligands that exhibit dual antagonism for delta-/mu-opioid receptors.

Studies by the inventors have shown that injected radioligand failed to cross the blood-brain barrier (BBB) of rats; therefore, these compounds could serve as radiotracers for assessing and locating certain carcinomas that contain high

levels of delta-opioid receptors, such as lung, breast and/or colon cancers. Since there is an increasing demand of radioligands for in vivo imaging of peripheral opioid receptors, this technology has the potential of enhancing current practices of PET imaging in oncology.

Available for licensing are compositions and methods of locating delta- and/or mu-opioid receptors located in peripheral cancers, such as in lung, breast, and/or colorectal cancer, using opiate radioligands.

Applications: Non-invasive tool for screening lung, breast, and/or colorectal cancers. Diagnostic tool for use in PET imaging.

Market: For 2007, it was projected that close to 1.5 million Americans would develop cancer.

PET imaging is steadily becoming a technique of choice in oncology so many of these patients will likely undergo scans several times during their treatment to assess the stage of their disease. This is supported by rising sales of FDG, which are expected to reach $933 million by 2012.

Development Status: Early stage.

Inventors: Lawrence H. Lazarus (NIEHS) *et al.*

Relevant Publication: KA Roth and JD Barchas. Small cell carcinoma cell lines contain opioid peptides and receptors. Cancer 1986 Feb 15;57(4):769–773.

Patent Status: U.S. Provisional Application No. 60/970,143 filed 05 Sep 2007 (HHS Reference No. E–317–2007/0–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The NIEHS Laboratory of Pharmacology, Medicinal Chemistry Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Elizabeth Denholm, PhD., Director, NIEHS Office of Technology Transfer, at 919–541–0981 or *denholme@mail.nih.gov* for more information.

Novel Isoform of KCNH2 for the Treatment of Schizophrenia

Description of Technology: Researchers at the NIH report the discovery and characterization of a novel isoform of the voltage-gated potassium channel KCNH2. This novel isoform is shown to control neurological firing and has implication as a genetic risk factor for schizophrenia. It is highly expressed in the hippocampus of schizophrenic patients and also in normal individuals who carry risk-associated alleles of KCNH2. This novel isoform may be a suitable target for drug development as is it minimally expressed in the heart with the potential to exert less adverse cardiovascular side-effects, which is often a consequence of currently available antipsychotic drugs.

Available for licensing and commercial development are nucleic acids, polypeptides and antibodies specific for this novel isoform, as well as methods of screening for therapeutic agents and predicting susceptibility to schizophrenia.

Applications: Potential new psychotherapeutic agent with less cardiac side-effects. Potential drug screening assay for identifying new psychotherapeutic drugs. Potential diagnostic tool for determining susceptibility of schizophrenia.

Market: Schizophrenia is among the most severe of the mental illnesses and has a lifetime prevalence of approximately 1% worldwide.

More than 2,000,000 Americans have schizophrenia and it accounts for 2.5% of U.S. health care costs and 75% of expenditures for long-term mental health.

Development Status: Early stage.

Inventors: Daniel R. Weinberger *et al.* (NIMH).

Patent Status: U.S. Provisional Application No. 60/920,220 filed 26 Mar 2007 (HHS Reference No. E–245–2006/0–US–01).

PCT Application No. PCT/US2008/057913 filed 21 Mar 2008 (HHS Reference No. E–245–2006/0–PCT–02).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The NIMH Clinical Brain Disorders Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize potassium channel isoform associated with schizophrenia. Please contact Suzanne Winfield at 301–402–4324/*winfiels@mail.nih.gov* for more information.

Dated: June 13, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–14257 Filed 6–23–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Research Grants in Diabetes, Endocrine and Metabolic Diseases.

Date: July 1–2, 2008.

Time: 8 a.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Stuart B. Moss, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1044, *mossstua@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurogenetics.

Date: July 8, 2008

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joseph G. Rudolph, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–435–2212, *josephru@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopaedics and Skeletal Biology.

Date: July 11, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.