Register.) Facilities providing mammography services using grants under other statutes will not qualify as government entities. FDA does not recognize, as a governmental entity, a facility providing Medicare/Medicaid services unless that facility qualifies as a governmental entity as described in the previous paragraph.

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA mails a bill and a ''Governmental Entity Declaration'' form (Form 3422) to the inspected facility. Facilities who believe they meet the governmental entity criteria complete the form and return it in lieu of the inspection fee payment. The bill sets forth the type of inspection conducted (annual or followup), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees are billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the parties to establish, through contract or otherwise, how the costs of facility inspections will be allocated.

If full payment is not received by the due date, a second bill is sent. At that time, interest begins to accrue at the prevailing rate set by the Department of the Treasury, a 6 percent late payment penalty is assessed in accordance with 45 CFR 30.13, and a $20 administrative fee is assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies, the reporting of delinquencies to commercial credit reporting agencies, and forwarding delinquent accounts to the Department of the Treasury. Any questions or concerns about the billing and collection procedures may be addressed to Billing Inquiries c/o Mammography Quality Assurance Program, P.O. Box 6057, Columbia, MD 21045, 1–800–838–7715.

VII. Request for Comments

Although the MQSA does not require FDA to solicit comments on fee exemption, assessment, and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views and information, as the agency continues to evaluate its fee assessment procedures.

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 comments 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following reference is 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.

1. U.S. Food and Drug Administration, MQSA Inspection Fees: Methodology and Fees for Fiscal Year 2008.

Dated: June 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13044 Filed 7–5–07; 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.

Potential Serum Bio-Markers for Alpha-Fetoprotein (AFP) Negative Hepatocellular Carcinoma

Description of Technology: This technology relates to improved methods of detecting hepatocellular carcinoma (HCC) by using new biomarkers. The overexpression of Gpc3, Mdk, SerpinI1, PEG–10 and QP–C correlates with the presence of HCC, even in small tumors. By comparing the expression levels of at least three of these markers in subject samples with their expression levels in control samples, the presence of HCC can be diagnosed. The method can also be used to monitor the progression, and regression of HCC.

HCC is a common and aggressive cancer with a high mortality rate. The high mortality rate stems from an inability to diagnose the cancer at an early stage in patients, due to the lack of available biomarkers for HCC. Currently, HCC is diagnosed by measuring the levels of serum alpha-fetoprotein (AFP); however, AFP is not always present in HCC tumors, especially small tumors.

Applications: Protein markers useful for screening HCC more accurately and with increased sensitivity; The proteins can also serve as prognostic and therapeutic response biomarkers.

Advantages: Highly sensitive, secretory markers that can be easily identified in patient serum; Markers can identify HCC in patients with small tumors that would previously go undetected.

Benefits: HCC affects 20,000 people in U.S. or over half a million worldwide every year and 90% of them die of the disease. Improving the quality of life and duration of life for people suffering from this disease will depend a lot on early detection of the disease and this technology can contribute significantly to that social cause. Furthermore, the cancer diagnostic market is estimated to grow to almost $10 billion dollars in the next 5 years.

Inventors: *Xin Wei Wang* (NCI) et al.

U.S. Patent Status: Pending PCT Application PCT/US2006/042591, published as WO 2007/053659 (HHS Reference No. E–333–2005/0–PCT–02).

Licensing Contact: David A. Lambertson, PhD; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize new biomarkers for hepatocellular carcinoma (HCC). Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Modification of Recombinant Anti-Tumor RNase (rapLR1) for Optimal Use in the Large Scale Manufacture of Stable and Potent RapLR1-Antibody Conjugates

Description of Technology: This technology involves modified rapLR1 molecules having an improved capacity for conjugation to targeting moieties. Previously, techniques for attaching wild-type rapLR1 to a targeting moiety required an excess of RNase, leading to high production costs. The inventors have now mutated specific amino acids in rapLR1 to allow a more efficient (and therefore less costly) conjugation reaction.

Members of the ribonuclease A (RNase A) superfamily, such as rapLR1, have the ability to efficiently kill a wide range of cancer cells. Ligand binding moieties such as antibodies or peptides can be used to target RNases to a particular cell or cell type that expresses a marker, e.g., a marker that is associated with cancer. The current invention provides rapLR1 molecules that have been genetically modified to contain a cysteine at a specific location that does not interfere with the enzymatic activity of the molecule. The inserted cysteine provides the advantage of a site-directed and specific attachment of rapLR1 to targeting moieties, which results in more efficient production of the therapeutic. This significantly reduces the cost of bringing rapLR1-related cancer therapeutics to market.

Applications: Targeted anti-cancer therapy molecules; Targeting moiety can be interchanged based on target cancer cells; Targeting any disease in which the cell is transformed and presents unique levels of cell surface markers.

Advantages: RapLR1 delivery, specificity and toxicity to cancer cells is increased by conjugation to a targeting moiety; Modified rapLR1 increases conjugation efficiency, making the preparation of the anti-cancer agents more cost effective without sacrificing specificity.

Benefits: Cancer is the second leading cause of death in the United States, with approximately 600,000 cancer-related deaths occurring in 2006 alone. Because rapLR1 can be used to treat a number of different cancers (depending on the targeting moiety), there is a powerful social benefit from this technology: Improving the duration and quality of life of a wide range of cancer patients. Furthermore, the cancer therapeutic market is expected to reach $27 billion by 2009. Because rapLR1 can now be efficiently conjugated to targeting moieties, there is an opportunity to occupy a significant niche in that predicted market, with lower cost to the licensee.

Inventors: Dianne L. Newton et al. (NCI).

U.S. Patent Status: Pending PCT Application PCT/US2006/038180, published as WO 2007/041361 (HHS Reference No. E–265–2005/0–PCT–02).

Licensing Contact: David A. Lambertson, PhD; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

Methods for Expression and Purification of Immunotoxins

Description of Technology: The invention concerns immunotoxins and methods of making the immunotoxins. Targeting of the immunotoxins occurs via an antibody that is specific to T cells. This allows the specific ablation of malignant T cells and resting T cells. The transient ablation of resting T cells can ''reset'' the immune system by accentuating tolerizing responses. As a result, the immunotoxin can be used to treat autoimmune disease, malignant T cell-related cancers, and graft-versus-host disease. The toxin portion of the immunotoxin is engineered to maintain bioactivity when produced in yeast, specifically *Pichia pastoris.* This system allows the production of dimeric antibody fragments with increased binding affinity and potency.

Applications: Immunotoxins produced by this method can be used for the treatment of autoimmune diseases such as multiple sclerosis, lupus, type I diabetes, aplastic anemia; Immunotoxins produced by this method can be used for treatment of T-cell leukemias and lymphomas such as cutaneous T cell leukemia/lymphoma (CTCL); Immunotoxins produced by this method can be used for increasing immune tolerance in patients requiring transplants/grafts.

Advantages: Method produces GMP quality immunotoxin and can be scaled up to industry scales; Modified toxin moiety has reduced glycosylation in this system, resulting in a more effective and efficient immunotoxin; Immunotoxin doesn't produce the deleterious side-effects seen with other methods of treating autoimmune disease, malignant T cell leukemia/lymphoma and graft-versus-host disease.

Benefits: New methods and compositions with limited side-effects have the potential to revolutionize treatment of autoimmune disease; provides an opportunity to capture a significant market share for the millions of people who suffer from an autoimmune disease.

Inventors: *David Neville* et al. (NIMH)

Patent Status: U.S. Patent Application No. 10/566,886 filed 01 Feb 2006, which published as U.S. 2006/0216782 on 28 Sep 2006 (HHS Reference No. E–043–1997/2–US–03); U.S. Patent No. 6,632,928 issued 14 Oct 2003 (HHS Reference No. E–044–1997/0–US–07); U.S. Patent Application No. 10/435,567 filed 09 May 2003, which published as 2003/0185825 on 02 Oct 2003 (HHS Reference No. E–044–1997/0–US–08); U.S. Patent Application No. 10/296,085 filed 18 Nov 2002, which published as 2004/0127682 on 01 Jul 2004 (HHS Reference No. E–044–1997/1–US–06); Foreign rights are also available.

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: David A. Lambertson, PhD; 301/435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Mental Health, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize methods of expression and purification of immunotoxins. Please contact David Neville at *davidn@mail.nih.gov* for more information.

Dated: June 28, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–13128 Filed 7–5–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Neurological Disorders and Stroke; 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 section 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.