SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Draft Guidance, Emergency Use Authorization of Medical Products” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P.O. Box 5156, Rockville, MD 20850, 301-796-3794, e-mail: Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 6, 2009 (74 FR 51285), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0595. The approval expires on January 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.


Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “The Mammography Quality Standards Act Requirements” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Leslie Kux, Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Draft Guidance, Emergency Use Management and Budget Approval; Activities; Announcement of Office of Management and Budget Approval; The Mammography Quality Standards Act Requirements” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Draft Guidance, Emergency Use Authorization of Medical Products” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P.O. Box 5156, Rockville, MD 20850, 301-796-3794, e-mail: Jonnalynn.capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 15, 2010 (75 FR 33811), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0309. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.


Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

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.

Immunotoxin for the Treatment of Neuroblastoma Relapse

Description of Technology: Immunotoxins are proteins which have two distinct domains: (1) An antibody or antibody binding fragment which is capable of recognizing a single specific cell surface protein and (2) a toxin domain which is capable of inducing cell death. Immunotoxins are currently being pursued as therapeutics because they specifically kill diseased cells while leaving essential, healthy cells alone. This increases the effectiveness of the therapy while reducing the appearance of side-effects. A particular immunotoxin that is being studied in clinical trials consists of an anti-CD22 antibody binding fragment and a mutated Pseudomonas exotoxin A. Although this immunotoxin is being explored primarily as a treatment for hematological malignancies, it can be used to treat any condition where CD22 is overexpressed on the cell membrane of diseased cells.

Neuroblastomas are malignant cancers that start in nerve tissue and primarily affect infants and children. Although frontline treatments for neuroblastoma are often effective, relapse frequently occurs in high risk cases. The most common form of relapse in neuroblastoma patients is caused by Neuroblastoma tumor initiating cells (NB–TIC). Therefore, if NB–TIC could be eliminated, high risk neuroblastoma patients could have a therapeutic option for preventing a relapse.

This invention concerns the discovery that NB–TIC expresses CD22. As a result, NB–TIC are susceptible to treatment with an anti-CD22 immunotoxin. By combining frontline
neuroblastoma treatments with anti-CD22 immunotoxins, both the primary neuroblastoma and cells capable of initiating a relapse can be eliminated. As a result, even high risk neuroblastoma patients should have an increased chance of surviving neuroblastoma.

Application: Treatment and prevention of neuroblastoma relapse.

Advantages:
- Increased therapeutic effectiveness with decreased non-specific killing of essential, healthy cells.
- Neuroblastoma relapse commonly begins in the bone marrow, an environment which is accessible to immunotoxins.
- Combined treatment addresses both the tumor and the cause of relapse, leading to more efficient treatments than frontline therapeutics alone.

Development Status: Preclinical stage of development for treatment of neuroblastoma relapse; immunotoxins have clinical data associated with treatment of hematological malignancies.

Inventors: Thiele (NCI) et al.

Development Status: Preclinical stage of development for treatment of neuroblastoma relapse; immunotoxins have clinical data associated with treatment of hematological malignancies.

Inventors: Thiele (NCI) et al.

Related Publications:


Licensing Status: Available for licensing.

Licensing Contact: Whitney A. Hastings; 301–451–7337; hastingsw@mail.nih.gov.

Chemokine-Tumor Antigen Fusion Proteins as Cancer Vaccines

Description of Technology: Available for licensing is a tumor vaccine that uses a chemoattractant (such as human chemokines CCL7 and CCL20) fused to a tumor antigen (including human mucin-1, a transmembrane protein that is aberrantly expressed in cancer; or single chain antibody expressed by B cell malignancy, or melanoma antigen gp100 expressed in human melanomas). The majority of tumor antigens are believed to be poorly immunogenic because they represent oncogene gene products or other cellular genes which are normally present in the host. As a result, poor immunogenicity has been a major obstacle to successful immunotherapy with tumor vaccines. Administration of this fusion chemokine and tumor antigen protein, or a nucleic acid encoding this fusion protein, elicits a tumor specific cellular and humoral immune response thereby providing a potent cancer vaccine.

Applications: Cancer immunotherapy.

Development Status: Proof of the concept and pre-clinical development have been successfully completed.

Market: The global cancer market is forecasted to reach US$40 billion by 2012. Cancer vaccine research is coming to fruition, with a number of products now in Phase III trials and 15 therapeutic cancer vaccines realistically expected to launch by 2013. The therapeutic vaccine market has the potential to mirror the growth seen in the monoclonal antibody market, and reach sales in excess of US$5 billion by 2012.

Inventors: Larry Kwak (NCI) and Aarya Biragyn (NIA) (both NCI at time of invention).

Related Publications:


**licensing Contact:** Patrick McCue, PhD; 301–435–5560; mccuepat@mail.nih.gov.

**Collaborative Research Opportunity:** The National Institute on Aging, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cancer vaccines that target skin antigen-presenting cells.

**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.

**Description of Invention:** Metabolite profiling identifies and measures changes in cellular metabolites as a means to determine a direct correlation between gene expression and changes in biological function. Investigators at the National Cancer Institute have identified a unique set of metabolite biomarkers associated with hepatocellular carcinoma (HCC), early stage HCC, HCC patient outcome and HCC stem-cell subtype. Subsets of this metabolite/gene signature can distinguish HCC tumors from normal tissues with 88–97% accuracy, identify early stage HCC patients with 62–78% accuracy, wherein early stage is defined as TNM stage I, prognose negative patient outcome, and identify a HCC stem cell subtype with 70–77% accuracy. These metabolites and gene surrogates are elements of the PI3K and MEK signaling networks which can potentially be targeted for therapeutic purposes.