In addition, CMS has physical safeguards in place to reduce the exposure of computer equipment and thus achieve an optimum level of protection and security for the IRIS. For computerized records, safeguards have been established in accordance with the Department of Health and Human Services (HHS) standards and National Institute of Standards and Technology guidelines, e.g., security codes will be used, limiting access to authorized personnel. Systems securities are established in accordance with the Department of Health and Human Services (HHS), Information Resource Management Circular #10, Automated Information Systems Security Program; CMS Automated Information Systems Guide, Systems Securities Policies, and OMB Circular No. A–130 (revised), Appendix III.

RETENTION AND DISPOSAL:

Records are maintained in a secure storage area with identifiers. Disposal occurs three years from the last action on the hospital's cost report, and should be coordinated with disposal of the reports.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Financial Integrity, Office of Financial Management, CMS, 7500 Security Boulevard, C3–14–00, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the systems manager who will require the system name, SSN, address, date of birth, sex, and for verification purposes, the subject individual's name (woman's maiden name, if applicable). Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Data for this system is collected from IRIS diskettes as transmitted by the hospitals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 02–18169 Filed 7–22–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0055]

Agency Information Collection Activities; Announcement of OMB Approval; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Infant Formula Recall Regulations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 6, 2002 (67 FR 39011), 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 0910–0188. The approval expires on July 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18557 Filed 7–22–02; 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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Methods for Treating Cancer in Humans Using IL–21

Patrick Hwu, M.D. and Gang Wang, Ph.D. (NCI)

U.S. Patent Application No. 60/368,438 filed on March 27, 2002

Licensing Contact: Jonathan Dixon; 301/496–7056 ext. 270; e-mail: *dixonj@od.nih.gov*

The present invention discloses the use of IL–21 for cancer therapy and/or cancer prevention. When compared to similar cytokines, IL–21 has shown substantial anticancer activity and reduced toxicity in murine models.

IL–21 belongs to the class I family of cytokines and is closely related to IL–2 and IL–15. Some cancer patients have shown significant response to administration of IL–2. However, IL–2 has also been associated with severe toxicity leading to a variety of undesirable side effects. This invention attempts to resolve the toxicity concerns and presents a new therapy for cancer prevention and treatment.

Amine Modified Random Primers for Microarray Detection

Charles Xiang and Michael J. Brownstein (NIMH)

DHHS Reference No. E–098–01/1 filed 11 Apr 2002

Licensing Contact: Cristina Thalhammer-Reyero; 301/496–7056 ext. 263; e-mail: *thalhamc@od.nih.gov*

The present invention relates to a new method for preparing fluorescence-labeled cDNA probes for DNA microarray studies, which only uses about 1/20th as much input RNA as the conventional methods require. The method allows making high quality probes from as little as 1 ug of total RNA without RNA or signal amplification. It is based on priming cDNA synthesis with random hexamers to the 5′ ends of which amino allyl modified bases have been added. Coupling of the fluorescent dye to the amine residues is performed after the cDNA is reverse transcribed. The method can be used in tandem with RNA amplification (and/or signal amplification) to label probes from 10 or fewer cells.

Furthermore, the invention also relates to a novel method to amplify RNA derived from single cells using T3-random 9mers and a new lysing method, which allow probe-labeling capabilities that are approaching the single cell level.

DNA Microarray technology has become one of the most important tools for high throughput studies in medical research with applications in the areas of gene discovery, gene expression and mapping. The suitability of DNA Microarray for profiling diseases and for identifying disease-related genes has also been also well documented. Companies like Affimatrix, Incyte and others have commercialized DNA microarrays, printed for a variety of applications. Most studies using DNA arrays involve preparation of fluorescent-labeled cDNA from the mRNA of the studied organism. The cDNA probes are then allowed to hybridize to the DNA fragments printed on the array, and the array is scanned and the data analyzed. Good results depend on a number of factors including high quality arrays and well-labeled probes. In order to achieve adequate sensitivity and reproducibility, probes have had to be prepared from rather large amounts of RNA using other methods.

Use of Lipoxygenase Inhibitors and PPAR Ligands as Anti-Cancer Therapeutic and Intervention Agents

James L. Mulshine (NCI) and Marti Jett
DHHS Reference No. E–069–01/0 filed 29 Jun 2001
Licensing Contact: Catherine Joyce; 301/496–7056 ext. 258; e-mail: *joycec@od.nih.gov*

This technology pertains to the use of inhibitors of the 5-lipoxygenase (5–LO) pathway for treating cancer. The use of 5–LO inhibitors for cancer growth inhibition has been previously described. The advancements in the technology that lead to the instant invention are the further characterization of the role of the 5–LO pathway in breast cancer growth as follows:

1. Growth stimulation of breast cancer cells with 5–HETE, a metabolite from the 5–LO pathway;

2. The upregulation of peroxisome proliferator-activated receptors, alpha and gamma (PPARα and PPARγ), in response to 5–LO inhibitors, and growth reduction of breast cancer cells with each of four PPAR ligands.

Therefore, the instant invention relates to a method of treating an epithelial derived cancer by administering an inhibitor to an enzyme that metabolizes arachidonic acid and a PPAR ligand, or derivative thereof.

The above-mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: July 11, 2002.

Jack Spiegel,

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

[FR Doc. 02–18511 Filed 7–22–02; 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, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

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RF Ablation Needle Tracked With Magnetic Position Sensing

Bradford J. Wood (CC), Filip Banovac, Kevin Cleary
DHHS Reference No. E–348–01/0 filed 01 Mar 2002
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov*

The invention is a method for using a newly developed position sensing device to determine the three-dimensional position of a needle for precision placement in interventional procedures. The method can be applied to accurate placement of a radiofrequency ablation probe for percutaneous treatment of neoplasms in the liver, kidney, or other solid organs, nodules or lymph nodes. The method incorporates a magnetic field based position sensing device that can track coils of only 0.9 mm diameter by 8 mm in length. These coils can be embedded in needles and other instruments to directly track the tip of these instruments. Based on a pre-operative CT scan, the position of these instruments relative to the anatomy can be displayed on a graphical user interface along with targeting assistance for the physician.

Direct Cell Target Analysis

Michael R. Emmert-Buck (NCI)
DHHS Reference No. E–100–01/0 filed 26 Apr 2002
Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov*

The invention is a novel, non-mechanical method for studying the molecular content of specific normal and/or diseased cell populations in a heterogeneous biological tissue section. Since the procedure is based on biomolecular targeting, it requires minimal effort on the part of the investigator, and can be easily and rapidly applied to a large number of cells. The invention can be applied in one of two ways. In the first scenario, a biological probe (i.e., antibody or oligonucleotide) is allowed to bind to a unique protein or mRNA expressed in the targeted cells. The probe is linked to an enzyme (such as reverse transcriptase or lactoperoxidase) that will specifically label the biomolecules in the targeted cell population. For example, if lactoperoxidase is utilized, the proteins in the targeted cells will subsequently be labeled with I-125, whereas, the proteins in the non-targeted cells will not be labeled and will be ''invisible'' in