and economically affiliated with the tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of contract health services.

Additionally, the regulations require that any redesignation of a CHSDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comment.

Pursuant to a Tribal Resolution 2000–32, dated March 9, 2000, the Tribe requested the IHS to redesignate their current CHSDA, which incorporates Mellette, Bennett, Todd, Trip and Cherry Counties in the State of South Dakota and Nebraska, to include Gregory and Lyman counties. In applying the aforementioned CHSDA redesignated criteria required by required by 42 CFR 136.22, the following findings are made:

(1) The Tribe enrollment and census records identify 519 tribal members residing in Gregory County and 0 tribal members residing in Lyman County.

(2) The Tribe has determined that contract health services would be available to all its members and members of other federally recognized tribes who reside in Gregory County and Lyman County having close social and economic ties with the Tribe.

(3) Gregory County is presently a CHSDA county for the Yankton Sioux Tribe. There are 159 Tribal members, of the 519 total, who are eligible for the Yankton Sioux CHS program because of close economic-social ties. The Yankton Sioux and Rosebud Sioux CHS programs will work together on the eligibility and CHS coverage on a case-by-case basis. Lyman County is presently a CHSDA county for the Lower Brule Sioux Tribe. There are 0 Tribal members who are eligible for the Lower Brule Sioux CHS program. The Lower Brule and Rosebud CHS program will work together on the eligibility and CHS coverage on a case-by-case basis if/when there are Rosebud Sioux residing within Lyman County.

(4) At this time, although Gregory County does not border the Rosebud Sioux's reservation, Gregory County was within the original boundaries of the reservation and continues to have a significant population of Rosebud Sioux. The Tribe chose to include Lyman County in the expansion even though, at the time of the analysis, there were no Rosebud Sioux tribal members residing in Lynn County. The close proximity to the original boundaries of the reservation was considered because there could be members residing in Lyman County in the future.

(5) The 519 tribal members residing in Gregory County presently utilize the Rosebud Indian Health Service facility's direct care services. Therefore, the clinical work load units will not be impacted. It is estimated that the current eligible contract health service population will be increased by 519 in Gregory County. The Rosebud CHS program has a recurring CHS funding base of $4,233,730. The formula used to determine what impact the additional 519 members, residing in Gregory County, would have on the Rosebud CHS fund is determined by using the Aberdeen Area's type of facility per capita of $327 × 519 = $169,713. The 0 number residing in Lyman County would have no impact at this time. The Rosebud Indian Health Service facility recognizes that there will be no additional CHS funding for this CHSDA expansion but they do not expect a significant impact on their present funding and support the tribe's CHSDA expansion and redesignation. The expansion and redesignation of the CHSDA to include both Gregory County and Lyman County is within the present available resources.

Accordingly, after considering the Tribe's request in light of the criteria specified in the regulations I am proposing to redesignate the CHSDA of the Tribe to consist of Bennett, SD, Cherry, NE, Mellette, SD, Todd, SD, Tripp, SD, Gregory, SD and Lyman, SD, Counties of South Dakota and Nebraska.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

Dated: March 10, 2003.

Charles W. Grim,

Assistant Surgeon General, Interim Director, Indian Health Service.

[FR Doc. 03–6398 Filed 3–17–03; 8:45 am]

BILLING CODE 4160–16–M

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.

Development of a Novel High Throughput Assay To Measure Cell Infection With Vaccinia Strains Expressing Reporter Genes

Hana Golding (FDA).

U.S. Provisional Patent Application 60/429,767 filed 27 Nov 2002.

Licensing Contact: Peter Soukas; 301/435–4646; *soukasp@od.nih.gov.*

Critical to developing a vaccine against viral infections is an assay to measure the neutralizing antibody present in blood of vaccine recipients. The currently available tests are labor intensive and require 5–6 days to complete. The inventors have designed a high throughput vaccinia neutralization assay, which offers several advantages over the assays that are currently used. It is completed in as little as 24 hours, it is sensitive, highly reproducible, requires only 50 μl of plasma and uses automated readout. This assay is based on the use of recombinant vaccinia virus (vSC56) expressing a bacterial gene coding for the enzyme b-galactosidase (b-Gal) under the control of a synthetic early/late promotor. Another recombinant virus expressing an inducible reporter gene (EGFP) is also being tested in neutralization assay. These assays may be of value in the clinical trials of new smallpox vaccines, for evaluations of new vaccinia immunoglobulin (VIG) and anti-viral agents under development. The technology itself may be adapted for construction of neutralization assays for other viruses and intracellular pathogens.

Method of Separating Recombinant Immunotoxin

Hua Jiang et al. (NCI).

DHHS Reference No. E–209–2002/0–US–01 filed 07 Nov 2002.

Licensing Contact: Jonathan Dixon; 301/435–5559; *dixonj@od.nih.gov.*

Over the past several years, dsFv-immunotoxins have generated significant interest in the research and commercial communities, as they have been shown to me more useful in certain therapeutic applications over intact antibody-immunotoxins and Fv-immunotoxins. dsFv-immunotoxins are created when a single-chain variable domain-toxin conjugate is associated with the complementary single-chain variable domain via one or more disulfide bonds to form a ''disulfide-stabilized'' Fv (dsFv)-immunotoxin.

Separation of dsFv-immunotoxin from its single-chain variable domain subunits (and any other contaminants) has thus far been achieved through a low yielding and relatively expensive process. The present invention discloses a new method of purifying dsFv-immunotoxins that has shown a three-fold increase in yield while at the same time keeping costs at a commercially reasonable level. As the demand for dsFv-immunotoxins increases, this method will give companies the ability to purify sufficient quantities to support their clinical trials and make their way to the commercial marketplace.

Optimization of Cardiac Contraction by Novel Human Kinase Mediated Differential Phosphorylation of Myosin

Dr. Neal D. Epstein (NHLBI).
DHHS Reference Nos. E–261–00/0 filed 12 Sep 2000 and E–261–00/2 filed 12 Sep 2001.
Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@od.nih.gov.*

This invention relates to the development of drugs that provide novel therapeutic interventions to increase the efficiency of failing hearts. It describes the cloning of the active cardiac kinase which modified the cardiac stretch-activation response and myofiber tension via phosphorylation of the beta myosin light chain molecules. These molecules are differentially phosphorylated by this kinase as a function of location to produce the spatial variation in myofiber mechanics that optimize cardiac torsion. The data in this invention indicate that targeting this cardiac light chain kinase could yield novel therapeutics to increase the efficiency of hearts failing from a variety of causes. This approach represents an alternative to present day therapeutics such as calcium blocking agents or digoxin, and thus may have the added benefit of providing therapeutics that are synergistic with present treatments.

This invention is described, in part, in Davis et al., Cell 2001 Nov 30; 107(5):631–41.

Methods of Screening for Risk of Cancer Using Human Lactoferrin DNA Probe or Primer

Christina Teng and Timothy Panella (NIEHS).
U.S. Patent 5,948,613 issued 07 Sep 1999.
Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@od.nih.gov.*

While normal breast ductal epithelium and neutrophilic granulocytes contain lactoferrin, their malignant counterparts frequently do not. The NIH announces primers or probes corresponding to the human lactoferrin gene, its promoter region, and its protein product, obtained from human breast tissue. The lactoferrin primer or probes can be used to screen for malignancy arising from tissues that normally secrete lactferrin, or as a test to check the recovery of a patient from a malignancy.

Dated: March 5, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–6366 Filed 3–17–03; 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.

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Methods for Prophylaxis and Treatment of HER–2/neu Tumors

John C. Morris, Jay A. Berzofsky, Yoshio Sakai, Jong-Myun Park, Masake Terabe (all of NCI).
Serial No. 60/422,395 filed 30 Oct 2002.
Licensing Contact: Susan S. Rucker; 301/435–4478; *ruckers@od.nih.gov.*

This application relates to methods for cancer prophylaxis and treatment. More particularly, the application relates to methods for the treatment and prophylaxis of cancers caused by the activity of the HER–2/neu/erbB–2 gene employing immunotherapy. Such cancers include breast cancers, cancers of the female genital tract and some cancers of the gastrointestinal tract.

The methods claimed involve the use of a HER–2/neu vaccine employing recombinant non-replicating adenovirus expressing a HER–2/neu/erbB–2 gene. In a preferred embodiment the vaccine comprises a recombinant non-replicating adenoviral vector encoding a HER–2/neu/erbB–2 gene that is expressed as a truncated HER–2/neu/erbB–2 protein. Antigen presenting cells, such as dendritic cells infected with the recombinant adenoviral vector, process and present the truncated HER–2/neu/erbB–2 protein, thereby stimulating an immune response. Preferred HER–2/neu/erbB–2 proteins contain regions of the extracellular domain and the transmembrane domain of the intact HER–2/neu/erbB–2 gene product and do not contain any tyrosine kinase domains.

This work has not yet been published.

gp100 Cancer Antigens

Steven A. Rosenberg et al. (NCI).
U.S. Patent 5,844,075 issued 10 Dec. 1998.
Licensing Contact: Jonathan Dixon; 301/435–5559; *dixonj@od.nih.gov.*

DHHS announces the availability of select gp100 cancer antigens for licensing. These antigens are composed of a class that fall under the following definition: gp100 P Core Peptide(s), meaning any gp100 peptide of nine (9) to fifteen (15) amino acids in length which is capable of eliciting an HLA–A2.1–restricted cytotoxic T cell response, and which comprises the formula $X_1X_2X_3PGPX_5TX_4$, where X_1 is any naturally occurring amino acid, X_2 is any hydrophobic aliphatic amino acid; X_3 is any naturally occurring amino acid; X_4 is any hydrophobic aliphatic amino acid, and X_5 is the amino acid V, C, I, L, or M.

GP100 is a tumor specific melanoma antigen. GP100 has been shown to be successful in stimulating the immune response to melanoma in humans.