Dated: November 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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.

Mice Lacking Expression of Chemokine Receptor CCR9 Generated by Gene Targeting (CCR9 KO Mice)

Description of Technology: Chemokines and their receptors are key regulators of thymocytes migration and maturation in normal and inflammation conditions. The chemokine CCL25 is highly expressed in the thymus and small intestine. CCR9, the receptor for CCL25, is expressed on the majority of thymocytes, indicating that CCR9 and its ligand may play an important role in thymocyte development. To investigate the role of CCR9 during lymphocyte development, CCR9 knockout mice were developed. Knockout mice had increased numbers of peripheral γδ-T cells but reduced numbers of αβ-T cells. In competitive transplantation experiments bone marrow from CCR9 knockout mice was much less efficient at repopulating the thymus than control (wild type) bone marrow. Thus, CCR9 KO mice are a model for studying thymocyte development and trafficking in the body. Additionally, as the ligand for CCR9 is highly expressed in the small intestine, CCR9 potentially plays a role in the specialization of immune responses in the gastrointestinal tract.

Applications: (1) Evaluate drugs aimed at blocking or augmenting lymphocyte trafficking; (2) A model for studying T cell development; (3) A model for studying immunological based gastrointestinal disorders.

Inventors: Paul E. Love (NICHD), Joshua M. Farber (NIAID), Shoji Uehara (NICHD).

Publications:

1. S Uehara *et al.* A role for CCR9 in T lymphocyte development and migration. J Immunol. 2002 Mar 15;168(6):2812–2819.

2. S Uehara *et al.* Characterization of CCR9 expression and CCL25/thymus-expressed chemokine responsiveness during T cell development: $CD3^{high}$CD69+ thymocytes and γδ TCR+ thymocytes preferentially respond to CCL25. J Immunol. 2002 Jan 1;168(1):134–142.

Patent Status: HHS Reference No. E–328–2006/0—Research Tool.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Jennifer Wong; 301/435–4633; *wongje@mail.nih.gov.*

mFPR2 Transgenic and Knockout Mouse Models for Alzheimer's and Other Inflammatory Diseases

Description of Technology: Human Formyl Peptide-Like Receptor 1 (hFPLR1) has been implicated in host defense for disease processes including Alzheimer's disease, infection, and other inflammatory diseases. hFPLR1 and its mouse homologue Formyl Peptide Receptor 2 (mFPR2) are G-protein coupled receptors that are expressed at high levels on phagocytic leukocytes, mediating leukocyte chemotaxis and activation in response to a number of pathogen- and host-derived peptides. Activation of hFPRL1/mFPR2 by lipoxin A4 may play a role in preventing and resolving inflammation. Also, hFPRL1/mFPR2 has been shown to mediate the chemotactic activity of amyloid β 1–42, a key pathogenic peptide in Alzheimer's disease.

Available for licensing are mice expressing the mFPR2 transgene on either the FVB or C58BL background, as well as mFPR2 knockout mice on the C57BL background. These mice are anticipated to be highly useful in the study of a wide variety of inflammatory, infectious, immunologic and neurodegenerative diseases.

Applications: (1) Drug development model for Alzheimer's disease and other inflammatory diseases; (2) Tool to probe the role of hFPRL1/mFPR2 in host responses in a variety of disease processes, including inflammatory, infectious, immunologic, and neurodegenerative disease.

Inventors: Ji Ming Wang *et al.* (NCI).

Related Publications:

1. K Chen, P Iribarren, J Hu, J Chen, W Gong, EH Cho, S Lockett, NM Dunlop, and JM Wang. Activation of Toll-like receptor 2 on microglia promotes cell uptake of Alzheimer disease-associated amyloid beta peptide. J Biol Chem. 2006 Feb 10;281(6):3651–3659.

2. H Yazawa, ZX Yu, Takeda, Y Le, W Gong, VJ Ferrans, JJ Oppenheim, CC Li, and JM Wang. Beta amyloid peptide (Abeta42) is internalized via the G-protein-coupled receptor FPRL1 and forms fibrillar aggregates in macrophages. FASEB J. 2001 Nov;15(13):2454–2462.

3. YH Cui, Y Le, W Gong, P Proost, J Van Damme, WJ Murphy, and JM Wang. Bacterial lipopolysaccharide selectively up-regulates the function of the chemotactic peptide receptor formyl peptide receptor 2 in murine microglial cells. J Immunol. 2002 Jan 1;168(1):434–442.

Patent Status: HHS Reference No. E–303–2006/0—Research Tool.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute—Frederick, Laboratory of Molecular Immunoregulation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize mFPR2 Transgenic and Knockout Mouse Models for Alzheimer's and Other Inflammatory Diseases. Please contact Betty Tong, Ph.D. at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Vaccine Production Strain for Acellular Pertussis Vaccine

Description of Technology: Available for licensing from the NIH is a vaccine production strain of Bordetella bronchiseptica that produces Bordetella pertussis toxin in high yield. The Bordetella bronchiseptica strain has been modified to eliminate expression of filamentous hemagglutinin, which typically has to be removed in purification of the toxin, thereby

reducing the yield of the active vaccine component. Immediately available for licensing is a strain that encodes a mutated pertussis toxin, which does not have to be chemically detoxified.

Application: Production of Bordatella pertussis toxin for acellular vaccine use.

Inventors: Tod Merkel, Jerry Keith, and Xiaoming Yang (NIDCR).

Patent Status: U.S. Patent No. 7,101,558 issued 05 Sep 2006 (HHS Reference No. E–159–1999/0-US–03).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov*.

HSV–2 Diagnostic

Description of Technology: The present invention relates to novel diagnostic methods for Herpes Simplex Virus Type 2 (HSV–2). HSV–2 infects approximately one fifth of adults in the United States and is the most common cause of genital ulceration. The invention relates to the detection of HSV–2 based on a transforming nucleic acid sequence and its protein product. This DNA sequence harbors the potential to induce the tumorigenic transformation of normal cells in *in vitro* and *in vivo* assays and thus will be useful as a means of prognostic evaluation in predicting the development of genital or cervical cancer. Current HSV–2 diagnostic tests relying on tedious viral culture and/or immunoassays that do not have the sensitivity and the specificity essential for diagnosis. Using PCR, the current invention will provide a superior method for viral detection and subtyping.

Application: HSV–2 diagnostic.

Inventors: Joseph A. DiPaolo (NCI–)

Publication: JA DiPaolo *et al.* Relationship of stable integration of herpes simplex virus-2 Bg/II N subfragment Xho2 to malignant transformation of human papillomavirus-immortalized cervical keratinocytes. Int J Cancer 1998 Jun 10;76(6):865–871.

Patent Status: U.S. Patent 6,617,103 issued 09 Sep 2003 (HHS Reference No. E–091–1999/0-US–03); CA Application 2,259,657 filed 30 Jun 1997 (HHS Reference No. E–091–1999/0-CA–04).

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

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The NCI Division of Basic Science is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HSV–2 Diagnostic. Please contact Betty Tong, Ph.D. at 301–594–4263 or *tongb@mail.nih.gov* for more information.

Dated: October 24, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–18885 Filed 11–7–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Availability of the Draft NTP Briefs on Genistein and Soy Formula; Request for Public Comments

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Request for comments.

SUMMARY: CERHR invites the submission of public comments on the draft NTP Briefs on Genistein and Soy Formula. The draft NTP Briefs are available from the CERHR Web site (*http://cerhr.niehs.nih.gov* see ''CERHR Reports & Monographs'') or in hardcopy from CERHR (see **ADDRESSES** below). Public comments will be considered during peer review and finalization of the NTP Briefs.

DATES: Written comments on the draft NTP Briefs on Genistein and Soy Formula should be received by December 8, 2006.

ADDRESSES: Public comments and any other correspondence should be addressed to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), (919) 541–3455 (phone), (919) 316–4511 (fax), or *shelby@niehs.nih.gov* (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

Genistein (CAS RN: 446–72–0) is a phytoestrogen found in some legumes, especially soybeans. Genistein is found in many food products, especially soy-based foods such as tofu, soy milk, and soy infant formula, and in some over-the-counter dietary supplements. Soy formula is fed to infants as a supplement or replacement for human milk or cow milk. On March 15–17, 2006, CERHR convened an expert panel to conduct evaluations of the potential reproductive and developmental toxicities of genistein and soy formula. The expert panel reports were released for public comment on May 5, 2006 (**Federal Register** Vol. 71, No. 94, pp. 28368, May 16, 2006). Following this public comment period, CERHR staff prepared draft NTP Briefs on Genistein and Soy Formula that provides in plain language:

- Background information on the substance(s).
- Findings of the expert panel.
- Discussion of any relevant data available after the expert panel meeting.
- NTP's conclusions on the potential for the substance to cause adverse reproductive and/or developmental effects in exposed humans.

Upon finalization, the NTP Briefs on Genistein and Soy Formula will be included in the CERHR Monographs on Genistein and Soy Formula. The draft NTP Briefs on Genistein and Soy Formula and related background materials, including the genistein expert panel report, soy formula expert panel report, and previously received public comments, are available on the CERHR Web site (*http://cerhr.niehs.nih.gov* see Genistein and Soy Formula under ''CERHR Reports & Monographs'').

Request for Comments

The NTP invites written public comments on the draft NTP Briefs on Genistein and Soy Formula. Any comments received will be posted on the CERHR Web site and considered during the peer reviews and finalization of the NTP Brief on Genistein and the NTP Brief on Soy Formula. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and submit comments to Dr. Shelby (see **ADDRESSES** above) for receipt by December 8, 2006.

Background Information on CERHR

The NTP established CERHR in June 1998 [**Federal Register**, December 14, 1998 (Volume 63, Number 239, page 68782)]. CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures.

CERHR invites the nomination of agents for review or scientists for its expert registry. Information about CERHR and the nomination process can be obtained from its homepage (*http://cerhr.niehs.nih.gov*) or by contacting Dr. Michael Shelby, CERHR Director (see **ADDRESSES**). CERHR selects chemicals