ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4238, Silver Spring, MD 20993–0002, 301–796–4830, Fax: 301–847–3541, E-mail: *peter.beckerman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2010 (75 FR 47820), FDA published a notice of a public meeting on the development of a generic drug user fee program. In that notice, FDA posed several questions related to a user fee for human generic drugs, and sought public input on such a program. The Agency received submissions and presentations from the public meeting, which are now posted on FDA's Web site. Some submissions arrived after the formal closing of the docket and FDA has decided to reopen the docket to permit public input on all the submissions.

Interested persons were originally given until October 17, 2010, to comment on the development of a generic drug user fee program. FDA is now reopening the docket to permit comment until December 6, 2010.

II. Request for Comments

Following publication of the August 9, 2010, meeting notice and request for comment, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 30 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. In light of this request, and the arrival of late submitted comments, FDA is reopening the comment period for an additional 30 days.

III. How To Submit Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: October 29, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–27824 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–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, 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.

System for Magnetic Resonance Spectroscopy of Brain Tissue for Pattern-Based Diagnostics

Description of Invention: Available for licensing and commercial development is a system for preprocessing magnetic resonance spectroscopy (MRS) data of brain tissue for pattern-based diagnostics. The MRS preprocessing system includes an MRS preprocessing module that executes an operation that normalizes MRS spectrum data, recalibrates and scales the normalized MRS spectrum data, and then renormalizes the scaled MRS spectrum data. The resulting preprocessed MRS data is used to assist in identifying abnormalities in tissues shown in MRS scans. Raw MRS spectrum data and scaling the raw MRS spectrum data is achieved by a plurality of weighting constants to generate a preprocessed MRS spectrum data. The method may also include providing raw MRS spectrum data, recalibrating the raw MRS spectrum data, and scaling the recalibrated MRS spectrum data by using a plurality of weighting constants to generate a preprocessed MRS spectrum data.

Applications

- MRI Imaging.
- Brain Imaging.
- Neurology.

Inventors: Jon G. Wilkes (FDA/NCTR), Dan A. Buzatu (FDA/NCTR), Pierre Alusta (FDA/NCTR), Bruce A. Pearce (FDA/NCTR), Richard Beger (FDA/NCTR), Inessa Im (FDA/NCTR).

Patent Status: U.S. Provisional Application No. 61/261,170 filed 13 Nov 2009 (HHS Reference No. E–298–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The FDA National Center for Toxicological Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize FDA's magnetic resonance spectroscopy technology in various imaging and diagnostic applications. Please contact Alice Y. Welch, PhD at 301–796–8449 or *alice.welch@fda.hhs.gov* for more information.

Cancer-Linked Sequences Encoding the A2BP1/FOX1 Gene

Description of Invention: Mesothelioma is a rare type of cancer in which malignant cells are found in the lining of the chest or abdomen. Symptoms are frequently misdiagnosed and an accurate diagnosis generally does not occur until advanced stages, and patients live on average nine to thirteen months after an accurate diagnosis. To date, there are no effective systemic treatments.

Researchers at the National Cancer Institute, NIH, have identified a recurrent alteration in the DNA sequence for ataxin-2 binding protein (A2BP1/FOX1) in human mesothelioma and colorectal cancers that is present in at least twenty percent (20%) of cancer cell lines and primary tumor samples. The sequence is not present in normal tissue, proving that it has arisen as an acquired somatic mutation in cancer. Furthermore, additional data suggests a possible role for the alteration in neurological diseases such as autism,

inherited mental retardation, and seizures.

This discovery offers a new approach for the diagnosis and early detection of cancer.

Applications: Development of assays for detection, diagnosis, or prognosis of diseases associated with chromosomal disruptions of the ataxin-2 binding protein 1 (A2BP1 or FOX1) gene, such as cancer and neurological disorders.

Development Status: Pre-clinical.

Inventors: Frederic J. Kaye (NCI).

Relevant Publication: Beroukhim R et al. The landscape of somatic copy-number alteration across human cancers. Nature 2010 Feb 18; 463(7283):899–905. [PubMed: 20164920]

Patent Status

- U.S. Provisional Application No. 61/121,997 filed 12 Dec 2008 (HHS Reference No. E–180–2008/0–US–01).
- International Patent Application No. PCT/US09/67502 filed 10 Dec 2009, which published as WO 2010/068757 on 17 Jun 2010 (HHS Reference No. E–180–2008/0–PCT–02).

Licensing Status: Available for licensing.

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

Insertion of Foreign Genes in Rubella Virus and Their Stable Expression in a Live, Attenuated Viral Vaccine

Description of Invention: Rubella virus (RUB) is the only member of the Rubivirus genus of the family Togaviridae. The RUB genomic RNA is a single-stranded, 9762-nt, positive-sense RNA that contains two long open reading frames (ORFs): A 5′-proximal ORF which encodes nonstructural proteins (NSP) that function primarily in viral RNA replication, including the RdRp, and a 3′-proximal ORF which encodes the virion structural proteins (SP), the capsid protein (C), and two envelope glycoproteins, E1 and E2. The genomic RNA serves as a template for synthesis of a complementary minus-strand RNA which is the template for synthesis of both the genomic RNA and the subgenomic (SG) RNA, from which the structural proteins are translated.

All earlier efforts at expressing foreign genes in rubella virus failed due to stability of the insert. The inventors have found a way to insert foreign genes into rubella virus such that the foreign genes can be expressed stably over many passages of the virus. More specifically, based on an earlier observation that rubella virus can tolerate a small deletion in the nonstructural genes and still replicate normally, the inventors' have used this deletion to make room for insertion of a foreign gene. Thus, the inventors have conceptualized and reduced to practice a new way to use the already-approved rubella vaccine as a viral vector to express the additional protein antigens of a second (or multiple other) viruses. This is highly advantageous because it allows for production of a live virus vaccine when attenuation is not possible for highly virulent viruses such as HIV.

Furthermore, another advantage of this vaccine is that virus titers in cell culture reach one thousand (1000) human doses per milliliter (ml) of culture supernatant. This is highly desirable for production of multiple millions of doses for the developing world. In the developed world, this vaccine could be substituted for the current vaccine at almost no cost and used to immunize against rubella plus the inserted antigen(s). Without vaccination, the average age of becoming seropositive for rubella is approximately nine (9) years old. This new vaccine could be given to one to two year olds with a booster at nine years old. Additionally, this vaccine is already approved, so the safe and immunogenic doses are already known.

Applications

- Vaccines for the prevention of rubella and other indications.
- Use of rubella vector for expression of foreign genes.

Advantages

- Novel vaccine candidate
- Rapid production time

Development Status: Preclinical studies have been conducted by the inventors.

Inventors: Ira Berkower and Angelo Spadaccini (FDA).

Patent Status

- U.S. Provisional Application No. 61/252,568 filed 16 Oct 2009 (HHS Reference No. E–156–2008/0–US–01).
- International Patent Application No. PCT/US2010/052948 filed 15 Oct 2010 (HHS Reference No. E–156–2008/0–PCT–02).

Relevant Publication: Spadaccini A, Vimik K, Ni Y, Prutzman K, Berkower I. Stable expression of a foreign protein by a replication-competent rubella viral vector. Vaccine. 2010 Feb 3;28(5):1181–1187. [PubMed: 19945412].

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@mail.nih.gov.*

Inhibition of Cell Motility, Angiogenesis and Metastasis

Description of Invention: The present invention relates to potent, highly selective antagonists of Grb2 Src homology-2 (SH2) domain binding. Grb2, through its SH2 domain, mediates growth factor driven cell motility *in vitro* and angiogenesis *in vivo.* These synthetic, small molecule antagonists have been shown to block cell motility stimulated by hepatocyte growth factor (HGF), fibroblast growth factor (FGF), epidermal growth factor (EGF), and vascular endothelial cell growth factor (VEGF). They also potently inhibit HGF- and VEGF-stimulated morphogenesis and angiogenesis, respectively, in several model systems. HGF stimulates mitogenesis, motogenesis and morphogenesis in a wide range of cellular targets during development and adulthood, and its signaling pathway is frequently over-activated in human cancers, including colon, gastric, breast, lung, thyroid and renal carcinomas, melanoma, several sarcomas as well as glioblastoma. The ability of HGF to initiate a program of cell dissociation and increased cell motility coupled with increased protease production promotes aggressive cellular invasion and is frequently linked to tumor metastasis.

Metastasis, the primary cause of death in most forms of cancer, is a multistep process whereby cells from the primary tumor spread systemically and colonize distant new sites. Blocking critical steps in this process could potentially inhibit tumor metastasis and dramatically improve cancer survival rates. The small, synthetic Grb2 SH2 domain antagonists described in this invention have been shown to inhibit the induced and spontaneous metastasis of melanoma- and prostate cancer-derived tumor cells in mice. These results establish a critical role for Grb2 SH2 domain-mediated interactions in the metastatic process and support the potential efficacy of this class of compound in reducing the metastatic spread of primary solid tumors in humans.

Applications and Modality: Inhibition of cell motility-dependent processes, including angiogenesis and metastasis, in several types of cancer such as prostate, colon, gastric, breast, lung, thyroid and renal carcinomas, melanoma and various sarcomas.

Development Status: In vivo and *in vitro* studies have been conducted on this technology.

Market

- Cancer is the second leading cause of death in the U.S.

• The worldwide incidence of new cancer patients is forecast to increase from 4.2 million cases in the major cancer markets in 2005 to 4.6 million in 2010.

• It is estimated that the worldwide cancer marker will be worth 85.3 billion in 2010.

Inventors: Donald P. Bottaro et al. (NCI).

Relevant Publications

1. Atabey N, Gao Y, Yao Z-J, Breckenridge D, Soon L, Soriano JV, Burke TR Jr, Bottaro DP. Potent blockade of Hepatocyte Growth Factor-stimulated cell motility, matrix invasion and branching morphogenesis by antagonists of Grb2 Src homology 2 domain interactions. J Biol Chem. 2001 Apr 27;276(17):14308–14314. [PubMed: 11278639].
2. Shi Z-D, Wei C-Q, Wang X, Lee K, Liu H, Zhang M, Vasselli J, Bottaro DP, Linehan WM, Yang D, Burke TR Jr. Macrocyclization in the design of tetra-tetrapeptide mimetics that display potent inhibition of Grb2 SH2 domain binding in whole cell systems. In: Peptide Revolution: Genomics, Proteomics Therapeutics. Chorev, M and Sawyer, TK, Eds. American Peptide Society, pp 515–517, 2003.
3. Soriano JV, Lui N, Gao Y, Yao Z-J, Ishibashi T, Underhill C, Burke TR Jr, Bottaro DP. Inhibition of angiogenesis by growth factor receptor bound protein 2-Src homology 2 domain bound antagonists. Mol Cancer Ther. 2004 Oct;3(10):1289–1299. [PubMed: 15486196].
4. Shi Z-D, Karki RG, Worthy KM, Bindu LK, Dharmawardana PG, Nicklaus MC, Bottaro DP, Fisher RJ, Burke TR Jr. Utilization of a nitrobenzoxadiazole (NBD) fluorophore in the design of a Grb2 SH2 domain-binding peptide mimetic. Bioorg Med Chem Lett. 2005 Mar 1;15(5):1385–1388. [PubMed: 15713392].
5. Kang S-U, Shi, Z-D, Worthy KM, Bindu LK, Dharmawardana PG, Choyke SJ, Bottaro DP, Fisher RJ, Burke TR Jr. Examination of phosphoryl-mimicking functionalities within a macrocyclic Grb2 SH2 domain-binding platform. J Med Chem. 2005 Jun 16;48(12):3945–3948. [PubMed: 15943469].
6. Shi Z-D, Peruzzi B, Dharmawardana PG, Leech T, Appella E, Worthy KM, Bindu LK, Fisher RJ, Bottaro DP, Burke TR Jr. Synthesis and use of C-terminally biotinylated peptidomimetics with high Grb2 SH2 domain-binding affinity. In: Understanding Biology Using Peptides, Blondelle SE (Ed), American Peptide Society, pp 208–209, 2005.
7. Dharmawardana PG, Peruzzi B, Giubellino A, Burke TR Jr, Bottaro DP. Molecular targeting of growth factor receptor-bound 2 (Grb-2) as an anti-cancer strategy. Anti-Cancer Drugs 2006 Jan;17(1):13–20. [PubMed: 16317285].
8. Liu F, Worthy KM, Bindu L, Giubellino A, Bottaro DP, Fisher RJ, Burke TR Jr. Utilization of achiral alkenyl amines for the preparation of high affinity Grb2 SH2 domain-binding macrocycles by ring-closing metathesis. Org Biomol Chem. 2007 Jan 21;5(2):367–372. [PubMed: 17205182].
9. Giubellino A, Gao Y, Lee S, Lee M-J, Vasselli JR, Medepalli S, Trepel JB, Burke TR Jr, Bottaro DP. Inhibition of tumor metastasis by a growth factor receptor bound protein Src domain-binding antagonist. Cancer Res. (Priority Report) 2007 Jul 1;67(13):6012–6016. [PubMed: 17616655].

Patent Status: U.S. Patent Application No. 11/525,672 filed 22 Sep 2006 (HHS Reference No. E–265–1999/2–US–01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The Urologic Oncology Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Grb2 SH2 domain antagonists as anti-cancer drugs. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: October 29, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–27912 Filed 11–3–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0132]

Guidance for Industry: Cellular Therapy for Cardiac Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Cellular Therapy for Cardiac Disease" dated October 2010. The guidance document provides sponsors who are developing cellular therapies for the treatment of cardiac disease with recommendations on the design of preclinical and clinical studies and on the chemistry, manufacturing and controls (CMC) information that should be included in an investigational new drug application (IND) for cellular therapy for cardiac disease. The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Somatic Cell Therapy for Cardiac Disease" dated March 2009.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for