suppositories, 12.5 mg and 25 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PHENERGAN (promethazine HCl) suppositories, 12.5 mg and 25 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15174 Filed 8–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0160]

Determination That Daranide (Dichlorphenamide) Tablets, 50 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Daranide (dichlorphenamide) Tablets, 50 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dichlorphenamide tablets, 50 mg.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated April 12, 2006 (Docket No. 2006P–0160/CP1), submitted under 21 CFR 10.30, Taro Research Institute requested that the agency determine whether Daranide Tablets, 50 mg, were withdrawn from sale for reasons of safety or effectiveness. Daranide (dichlorphenamide) Tablets, 50 mg, are the subject of approved NDA 11–366 held by Merck & Co., Inc. (Merck). Daranide is indicated for adjunctive treatment of glaucoma. Merck discontinued marketing Daranide Tablets, 50 mg, in June 2002, and they were moved to the ''Discontinued Drug Product List'' section of the Orange Book.

The agency has determined that Daranide Tablets, 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Daranide Tablets, 50 mg, were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined in this notice, Daranide (dichlorphenamide) Tablets, 50 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Daranide (dichlorphenamide) Tablets, 50 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Daranide (dichlorphenamide) Tablets, 50 mg, may be approved by the agency as long as they comply with relevant legal and regulatory requirements. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 30, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15230 Filed 8–3–07; 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, 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.

Methods for Determining Hepatocellular Carcinoma Subtype and Detecting Hepatic Cancer Stem Cells

Description of Technology: Hepatocellular carcinoma (HCC) is the third leading cause of cancer death worldwide, and it is very heterogeneous in terms of its clinical presentation as well as genomic and transcriptomic patterns. HCC can originate from both adult hepatocytes and hepatic progenitor cells. The extent of progenitor cell activation and the direction of differentiation are correlated with the severity of the disease. HCC patient variability indicates that HCC comprises several biologically distinct subtypes. This heterogeneity and the lack of appropriate biomarkers have hampered patient prognosis and treatment stratification.

Available for licensing are microRNA biomarkers that are associated with four HCC subtypes: hepatic stem cell-like, bile duct epithelium-like, hepatocytic progenitor-like, and mature hepatocyte-like. One unique profile is associated with HCC with features of liver stem cells and poor patient prognosis. It has both diagnostic and therapeutic value in the management of HCC patients.

Applications: A diagnostic assay where HCC treatment can be individualized according to patient HCC subtype; An assay for HCC to prognose patient survival; Therapeutic compositions that target subtype specific HCC.

Market: HCC is the third leading cause of cancer death worldwide; HCC is the fifth most common cancer in the world; Post-operative five year survival rate of HCC patients is 30–40%.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Xin Wei Wang (NCI) *et al.*

Publications:

1. Presented at Keystone Symposia on MicroRNA and Cancer in June 2007.

2. R Garzon *et al.* MicroRNA expression and function in cancer. Trends Mol Med. 2006 Dec;12(12):580–587.

Patent Status: U.S. Provisional Application No. 60/942,833 filed 08 Jun 2007 (HHS Reference No. E–215–2007/0–US–01).

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

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

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Isolation, Cloning, and Characterization of Novel Adeno-Associated Virus Serotypes

Description of Technology: Adeno-associated viruses (AAV) are used in gene delivery, but with limited success due to toxicity. The novel AAVs described in this technology may be more effective and useful in gene therapy applications.

This invention relates to new adeno-associated viruses (AAV), vectors and particles derived therefrom and also provides methods for delivering specific nucleic acids to cells using the AAV vectors and particles. The inventors cloned and sequenced the genomes of AAVs found in twelve (12) simian adenovirus isolates and determined that the AAVs were novel. Ten (10) of these isolates had high similarity to AAV1 and AAV6 (>98%). Despite the high homology to AAV6, these novel AAVs demonstrated distinct cell tropisms and reactivity towards a panel of lectins, suggesting that they may use a distinct entry pathway.

Applications: AAVs can be used as delivery systems in gene therapy; AAV's also have gene transfer applications.

Advantages: Vectors based on these new AAV serotypes may have a different host range and different immunological properties, thus allowing for more efficient transduction in certain cell types than previously used AAV.

Benefits: Gene therapy has tremenous potential in treating several life threatening diseases, and this technology has the potential to benefit millions of patients that could benefit from the proper use of gene therapy treatments. Additionally, the gene therapy market is now a multi-million dollar industry can substantially benefit from the use of this technology.

A range of licensing opportunities exist, including material licenses, commercial licenses, nonexclusive and exclusive licenses, as well as fields of use directed towards clinical applications. Please see the Office of Technology Transfer website for more information (*http://www.ott.nih.gov*).

Inventors: Michael Schmidt (NIDCR), John A. Chiorini (NIDCR), *et al.*

U.S. Patent Status: Pending PCT Application PCT/US2006/017157, published as WO 2006/119432 (HHS Reference No. E–179–2005/0–PCT–02).

Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research, Gene Therapy and Therapeutics Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize adeno-associated viruses. Please contact David W. Bradley, Ph.D. at *bradleyda@nidcr.nih.gov* for more information.

Serum Autoantibody for Cancer Diagnostics

Description of Technology: The invention demonstrates that the approach of autoantibody analysis provides a valuable approach for cancer diagnosis. Detecting serum autoantibodies against extracellular form of protein kinase A (ECPKA) can effectively diagnose cancer.

The technology describes compositions and methods for detecting autoantibodies against an ECPKA for the diagnosis of cancer. Because ECPKA is secreted from cancer cells at higher rate than normal cells, the formation of serum autoantibodies to ECPKA in cancer patients is greater. A highly sensitive enzyme immunoassay that measures the presence of anti-ECPKA autoantibody in serum of cancer patients can therefore be used for cancer diagnosis.

Application: ECPKA-autoantibody-based immunoassay method provides an important diagnostic procedure applicable for the detection of various cancers.

Advantages: Highly sensitive and specific immunoassay developed for anti-ECPKA antibody is more sensitive and specific than results from other current assays that detect only antigen activity; high statistical correlation betweeen the presence of serum-autoantibody directed against ECPKA and presence of cancer.

Benefits: Early detection of cancer and this technology can contribute

significantly to improving the clinical management of cancer and thus the quality of life for people suffering from the disease. Furthermore, the cancer diagnostic market is estimated to grow to almost $10 billion dollars in the next 5 years, providing a significant financial opportunity.

Inventors: Yoon S. Cho-Chung (NCI).

U.S. Patent Status: U.S. Patent Application No. 10/592,040 (HHS Reference No. E–081–2004/2–US–02); Foreign Rights are also available.

Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

A New Series of Thalidomide Analogs That Have Potent Anti-Angiogenic Properties

Description of Technology: This technology describes synthesis of several novel tetrahalogenated thalidomide derivatives that are potentially more anti-angiogenic than thalidomide. More specifically, two series of analogs based on two major common pharmacophores have been synthesized. One series preserves the thalidomide common structure, while the other series contains a different common structure (tetrafluorobenzamides). Several analogs from both series have shown significant anti-angiogenic properties, *in vitro.*

Applications: The novel thalidomide derivatives have therapeutic potential for a broad spectrum of cancer related diseases alone, or in combination with existing therapies. The compounds can also be useful for the treatment of autoimmune diseases.

Advantages: Superior anti-angiogenic and anti-cancer activity when compared with thalidomide; *In vitro* data supports use in multiple cancer types.

Benefits: Cancer is the second leading cause of death in the United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2007. Improving the quality of life and duration of life of cancer patients will depend a lot on chemotherapies with reduced toxicity and this technology can contribute significantly to that social cause. Furthermore, the technology involving novel anti-angiogenic small molecule cancer therapy technology has a potential market of more than $2 billion.

Inventors: William D. Figg (NCI) *et al.*

U.S. Patent Status: Pending PCT Application PCT/US2007/008849 (HHS Reference No. E–080–2006/0–PCT–02).

Licensing Contact: David A. Lambertson, Ph.D.; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

Dated: July 30, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–15168 Filed 8–3–07; 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, 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.

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Immortalized Cell Line for Retroviral Studies

Description of Technology: This technology describes immortalized human umbilical cord-blood T lymphocytes transformed with the retrovirus human T-cell leukemia-lymphoma virus (HTLV). These cells contain the HTLV genome and synthesize viral RNA but are restricted in their expression of viral structure proteins. This cell line should be useful in the study of retrovirus expression. Please visit the NIH AIDS Research and Reference Reagent Program Web site (*http://www.aidsreagent.org; catalog #404*) for additional information.

Applications: Viral expression studies; Study of viral proteins and nucleic acids involved in T-cell immortalization.

Inventors: Genoveffa Franchini (NCI).

Publications:

1. SZ Salahuddin *et al.* Restricted expression of human T-cell leukemia—lymphoma virus (HTLV) in transformed human umbilical cord blood lymphocytes. Virology 1983 Aug;129(1):51–64.

2. NIH AIDS Research and Reference Reagent Program Web site.

Patent Status: HHS Reference No. E–272– 2007/0—Research Tool.

Licensing Status: Available for licensing.

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

Device and Method for Protecting Against Coronary Artery Compression During Transcatheter Mitral Valve Annuloplasty

Description of Technology: Catheter-based mitral valve regurgitation treatments that use a coronary sinus trajectory or coronary sinus implant can have unwanted effects because the coronary sinus and its branches have been found to cross the outer diameter of major coronary arteries in a majority of humans. As a result, pressure applied by any prosthetic device in the coronary sinus (such as tension on the annuloplasty device) can compress the underlying coronary artery and induce myocardial ischemia or infarction.

Available for licensing and commercial development are devices and methods that avoid constricting coronary artery branches during coronary sinus-based annuloplasty. These devices and methods protect coronary artery branches from constriction during trans-sinus mitral annuloplasty. The device protects a coronary vessel from compression during mitral annuloplasty in which an annuloplasty element, such as a tensioning device, extends at least partially through the coronary sinus over a coronary artery. The device is a surgically sterile bridge configured for placement within the coronary sinus at a location where the coronary sinus passes over a coronary artery, so that the protection device provides a support for a mitral annuloplasty element, such as a compressive prosthesis, including a tension element when it is placed under tension. The protection device has an arch of sufficient rigidity and dimensions to support the tensioning element over the coronary artery, redistribute tension away from an underlying coronary artery, and inhibit application of pressure to the underlying artery, for example when an annuloplasty tension element is placed under tension during mitral annuloplasty.

In particular, the protective device can be a support interposed in the