Evaluation and Research (mail stop 5411), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEAs that FDA reviewed (Refs. 1 and 2) and FDA's evaluation of the TEAs (Refs. 3 and 4) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) (section 301(j) of the Federal Food, Drug, and Cosmetic Act) was deleted from the TEAs before they were placed on public display.

II. Request for Comments, Data, and Information

FDA has determined that the information submitted in this TEA satisfies the criteria of § 330.14(b). FDA will evaluate bisoctrizole, up to 10 percent, and bemotrizinol, up to 10 percent, as sunscreen single active ingredients and in combination with other existing monograph sunscreen active ingredients, for inclusion in the monograph for OTC sunscreen drug products (21 CFR part 352). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of these ingredients as single active ingredients for this use so that FDA can determine whether they can be GRAS/E and not misbranded under recommended conditions of OTC use. Additional data should be included to establish the safety and effectiveness of sunscreen drug products containing a combination of bisoctrizole and/or bemotrizinol with other existing sunscreen monograph active ingredients.

Neither of the TEAs included an official or proposed United States Pharmacopeia-National Formulary (USP–NF) drug monograph. According to § 330.14(i), an official or proposed USP–NF monograph for each ingredient must be included as part of the safety and effectiveness data for these ingredients. Interested parties should provide an official or proposed USP–NF monograph for each ingredient.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments, data, and information. Submit three copies of all comments, data, and information. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. Marketing Policy

Under § 330.14(h), any product containing the conditions for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA's for bisoctrizole submitted by CIBA Specialty Chemicals Corp., April 11, 2005.

2. TEA's for bemotrizinol submitted by CIBA Specialty Chemicals Corp., April 11, 2005.

3. FDA's evaluation and comments on the TEA for bisoctrizole.

4. FDA's evaluation and comments on the TEA for bemotrizinol.

Dated: November 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23576 Filed 12–2–05; 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.

Modified Recombinant Anti-Tumor RNase

Dianne L. Newton, David F. Nellis, Susanna M. Rybak (NCI)

U.S. Provisional Application filed 30 Sep 2005 (HHS Reference No. E–265–2005/0-US–01)

Licensing Contact: Jesse Kindra; 301/435–5559; *kindraj@mail.nih.gov*.

Members of the ribonuclease A (RNase A) superfamily such as Onconase® or rapLR1 have potential for clinical use either alone, combined with drugs, or as the toxic component of targeted therapy. In targeted therapies,

the RNase is conjugated to a targeting moiety, such as an antibody. Typically the RNase is chemically modified before it can be linked to another molecule. These methods usually require a large excess of unmodified RNase. The current invention provides genetically modified thiol-containing RNase molecules that can be used in much lower amounts to generate chemical conjugates. Additionally, the inserted thiol group provides the advantage of a site-directed and specific attachment of the RNase to targeting moieties. The invention also provides methodologies for generating cysteine-modified RNase conjugates and methods of using such conjugates.

Methods and Compositions for the Inhibition of SARS-CoV Replication Propagation and Transmission

Sharon M. Wahl and Gang Peng (NIDCR)
U.S. Provisional Application No. 60/713,724 filed 06 Sep 2005 (HHS Reference No. E–253–2005/0-US–01)
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial development is a method of inhibiting SARS-CoV replication, propagation and transmission using 2-cyano-3,12-dioxooleana-1,9-dien-28-oic (CDDO). Severe acute respiratory syndrome (SARS) is an infectious atypical pneumonia that has recently been recognized in patients in 32 countries and regions. The atypical pneumonia with unknown etiology was initially observed in Guangdong Province, China. This observation was followed by reports from Hong Kong, Vietnam, Singapore, Canada and Beijing of severe febrile respiratory illness that spread to household members and health care workers. This disease was later designated ''severe acute respiratory syndrome (SARS)'' by the World Health Organization (WHO). Until May 19, 2003, a cumulative total of 7,864 SARS cases were reported to WHO from 29 countries. A total of 643 deaths (case-fatality proportion: 8.2%) were reported.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Methods of Treating and Preventing Renal Cancer Using a Dimethane Sulfonate Compound

Drs. Susan Mertins, David Covell and Geoffrey Patton (STB, NCI-Fredrick), Melinda Hollingshead (BTB, DTB, NCI-Fredrick), B. Rao Vishnuvajjala (PRB, DTP, NCI-Bethesda), and Susan Bates (CTB, CCR, NCI-Bethesda).
HHS Reference No. E–249–2005/0-PCT–01
Licensing Contact: George G. Pipia; 301/435–5560; *pipiag@mail.nih.gov.*

Currently only a few small molecule inhibitors are effective in patients with renal cell carcinoma. Approximately 30,000 patients per year are diagnosed with this disease but many of them are untreatable because of intrinsic drug resistance, and efficient drug transport and detoxification mechanisms. This invention described and claimed in the patent application describes a series of dimethane sulfonate compounds based on NSC 281612 that are suitable for the treatment of renal cancer. Compositions comprising a pharmaceutically-acceptable carrier and a compound, or a salt suitable for use in the treatment or prevention of renal cancer are also described. The anti-tumor activity of NSC 281612 has been established in vivo against human renal tumor xenografts in mice. Suitable dosing and administration schedules for treatment of renal tumors have also been determined in this study.

Noncovalent HIV Env-CD4 Complexes for Generation of Broadly Neutralizing Antibodies

Jinhai Wang and Michael Norcross (FDA)
U.S. Provisional Application No. 60/711,985 filed 25 Aug 2005 (HHS Reference No. E–173–2005/0-US–01)
Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov.*

HIV vaccine technology based on HIV envelope protein (Env) have been less successful than anticipated to date. One possible reason for this is the potential conformational masking of neutralizing epitopes. The current technology combines HIV Env and cell surface polypeptides CD4 in non-covalent complexes to expose epitopes not present on the uncomplexed Env molecules. These complexes can thus be used to elicit neutralizing antibodies when used as vaccines, immunogenic compositions or immunotherapies. The CD4 inducing epitopes found in regions of the virus that are most conserved across clades are unmasked, thus making this technology potentially effective against HIV viruses from several clades. Additionally, cell surface polypeptide CD4 is in its native conformation and masked by Env, therefore it is unlikely to induce autoantibodies.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors. If you are interested in additional information on this collaborative opportunity, please contact Ms. Beatrice A. Droke at *bdroke@oc.fda.gov.*

Synthesis of Indenoisoquinoliniums and Methods of Use

Yves Pommier *et al.* (NCI).
PCT Application No. PCT/US2005/08491 filed 15 Mar 2005 (HHS Reference No. E–058–2005/0-PCT–02).
Licensing Contact: George G. Pipia; 301/435–5560; *pipag@mail.nih.gov.*

The technology relates to compounds and methods for treating cancer. Specifically, novel Topoisomerase I (Top I) inhibitors are disclosed. Top I is a DNA-modifying enzyme whose activity is required for viability of rapidly dividing cells such as cancer cells. Top I is a target of the potent anti-cancer drug Camptothecin, which inhibits Top I activity. However, camptothecin-based cancer therapies can produce side effects caused by toxicity of camptothecin.

The disclosed compounds are substituted indenoisoquinolinium compounds that inhibit Top I activity. The compounds exhibit anti-cancer activity and have chemical properties that may facilitate the development of novel anti-cancer therapies with reduced toxicity.

Confocal Fiber-Optic Laser Method for Intraocular Lens Power Measurement

Ilko K. Ilev (FDA).
U.S. Provisional Application No. 60/668,239 filed 03 Mar 2005 (HHS Reference No. E–039–2005/0-US–01)
Licensing Contact: Michael Shmilovich; 301/435–5019; *shmilovm@mail.nih.gov.*

Available for licensing and commercial development is a novel apertureless fiber-optic laser confocal design. Intraocular lens (IOL) dioptic power is a fundamental parameter whose precise measurement is of critical importance for characterizing and evaluating the effectiveness and safety of IOL's. The present invention relates to a simple, accurate, objective, quick and relatively inexpensive method for IOL power measurement. The principle of operation of this method is based on an apertureless fiber-optic laser confocal design. The key element in this design is a single-mode optical fiber coupler that simultaneously performs several essential functions. First, it provides effective launching and delivery of the input laser emission. Second, the fiber tip serves as a point light source used

for formation of a collimated Gaussian laser beam profile for IOL testing. Third, the tip serves as a highly sensitive point receiver of the back reflectance laser emission. Fourth, the fiber coupler provides delivery of the spatially separated back reflected laser emission to a detector system. The combination of these unique features of the confocal fiber-optic laser method provides high accuracy (exceeding 1 μm) in spatially locating the IOL focal point and measuring the IOL power. A unique feature of this method is that it allows for measurement of a wide range of both positive and negative powers including high-magnification IOL's with power greater than ±20 diopters. The simple and high-sensitive IOL power testing method will provide the CDRH/FDA and the scientific community with an independent source of measurement data and information for evaluating the effectiveness and safety of novel IOL products.

Minimally Immunogenic Variants of SDR-Grafted Humanized Antibody CC49 and Their Use

Syed Kashmiri (NCI), Jeffrey Schlom (NCI), and Eduardo Padlan (NIDDK)
U.S. Provisional Application No. 60/493,903 filed 29 Aug 2003 (HHS Reference No. E–323–2003/0-US–01) and PCT Application No. PCT/US04/28004 filed 27 Aug 2004 (HHS Reference No. E–323–2003/0-PCT–02).
Licensing Contact: Michelle Booden; 301/451–7337; *boodenm@mail.nih.gov*.

Tumor Associated Glycoprotein 72 (TAG)–72 is an oncofetal antigen expressed on a majority of human carcinomas, including colorectal, gastric, pancreatic, breast, lung, and ovarian. The murine monoclonal antibody (mAb) CC49 specifically recognizes TAG–72 and has a higher affinity for TAG–72 than its predecessor, B72.3.

The present invention relates to humanized monoclonal antibodies that have high binding affinity for the tumor-associated glycoprotein (TAG)–72 with minimal immunogenicity. This anti-TAG–72 antibody binds to the same epitope as the CC49 murine variant developed at the National Cancer Institute. The variants of CC49 described in this patent application have been shown to have a decreased immune response, with comparable binding affinity, than the parent murine antibodies.

These variants have potential benefits for use in the detection and/or treatment of a range of human carcinomas. Certain fields of use may not be available. Please contact OTT for information regarding the availability of specific fields of use. This variant was published in Kashmiri *et al.*, ''Minimizing Immunogenicity of the SDR-grafted Humanized Antibody CC49 by Genetic Manipulation of the Framework Residues,'' Molecular Immunology, 40 (2003), 337–349.

Restenosis/Atherosclerosis Diagnosis, Prophylaxis, and Therapy

Toren Finkel *et al.* (NHLBI)
U.S. Patent No. 6,183,752 issued 06 Feb 2001 (HHS Reference No. E–258–1994/0-US–01)
Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov.*

This technology relates to the compositions and methods for the diagnosis, prevention, and therapy of restenosis and atherosclerosis. It involves the use of an agent for decreasing viral load, preferably a vaccine, against cytomegalovirus (CMV) and p53, including a method for providing the therapy and administering the agent. This invention thus relates to stimulating an immune response, preferably a cellular immune response, directed against CMV and p53 to inhibit or prevent restenosis, atherosclerosis, and smooth muscle proliferation. Therefore, the technology offers methods for inducing cell death with the purpose of inhibiting smooth muscle proliferation as a means of preventing or treating restenosis and atherosclerosis.

Dated: November 14, 2005.

Steven M. Ferguson,

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

[FR Doc. E5–6802 Filed 12–2–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Mitotic Spindle ASPM as a Diagnostic Marker for Neoplasia and Uses Thereof

Paul K. Goldsmith, Vladmir Larionov, Natalay Kouprina and John I. Risinger (NCI)
U.S. Provisional Application No. 60/696,212 filed 01 Jul 2005 (HHS Reference No. E–210–2005/0–US–01)
Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

Cancer is responsible for approximately 23% of deaths in the United States of America. A high percentage of these deaths are caused by the lack of a precise diagnostic method that can detect malignancy in a particular tissue at an early stage. This invention provides for diagnostic methods, compositions, and kits that are useful for identifying neoplasia by measuring Abnormal Spindle-like Microcephaly associated (ASPM) expression in a patient sample. The ASPM gene is the human ortholog of the Drosophila melanogaster 'abnormal spindle' gene (asp), which is essential for normal mitotic spindle function in embryonic neuroblasts. By measuring ASPM expression levels one can also determine if a particular subject has a higher propensity to develop neoplasia. This invention is particularly useful in detecting neoplasia in hard to diagnose cancers like ovarian and uterine cancer.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Monoclonal Antibodies That Bind or Neutralize Hepatitis B Virus

Robert H. Purcell (NIAID) *et al.*
U.S. Provisional Application No. 60/644,309 filed 14 Jan 2005 (HHS Reference No. E–144–2004/0-US–01)
Licensing Contact: Chekesha S. Clingman; 301/435–5018; *clingmac@mail.nih.gov.*.

Hepatitis B virus (HBV) chronically infects over 300 million people worldwide. Many of them will die of chronic hepatitis or hepatocellular