TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Guidance	1	2	2	30	60

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The use of VMAC for resolving scientific disputes represents a new process for CVM. Although the procedures for requesting dispute resolution by a scientific advisory committee as set forth in the final guidance document are new, CVM estimates that the number of respondents who would submit requests would not increase. The number of hours per respondent (30) encompasses a wide range depending on the dispute involved. The estimate was based on discussions with industry and is an average of hours per respondent.

Dated: March 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5040 Filed 3–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 22, 2005, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation by the Office of Surveillance and Biometrics outlining their responsibility for the review of postmarket study design. The committee will also hear an update on the status of recent devices brought before the committee. The committee will discuss and make recommendations on a premarket notification submission for a coronary proximal anastomosis device. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 7, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 7, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240–276–0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 7, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–5039 Filed 3–14–05; 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, DHHS.

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.

Karyotypic Complexity as a Determinant of Anti-Cancer Drug Activity

Ilan R. Kirsch and Anna V. Roschke (NCI).

U.S. Provisional Patent Application filed 04 Feb 2005 (DHHS Reference No. E–101–2005/0–US–01).

Licensing Contact: Michelle A. Booden; 301/451–7337; *boodenm@mail.nih.gov*.

The recent clinical introduction of small molecule inhibitors that target single molecules as effective anticancer therapies underscores the potential of patient specific therapeutic interventions. However, the definition of a cancer specific target need not be a single transforming or survival-related gene or gene product. Another targetable and relatively irreversible cellular state might be the complexity and instability of the chromosomal complement of cancer cells. Structural and numerical chromosomal alterations are present in most neoplasms and karyotypic complexity is associated with a poor clinical prognosis as well as aggressive and distinctive histopathologic features.

The present invention describes methods for the selecting candidate compounds for evaluation for the treatment of cancer by defining the karyotypic complexity and heterogeneity in human cancer cells based on three components of genomic anatomy: ploidy, numerical chromosome changes, and structural chromosome rearrangements. Measures of complexity include the number of chromosomal rearrangements present in a cell line (structural complexity, SC) and the number of chromosome deviations from the ploidy level (numerical complexity, NC). Measures of cell-to-cell chromosomal variability, which reflect the degree of ongoing instability, include numerical heterogeneity (NH) and structural heterogeneity (SH). Utilizing the methods claimed in the this application, a number of chemical compounds were identified and later determined to have increased cytotoxicity toward cancer cell lines with a specific karyotypic complexity.

The positive correlations between drug sensitivity and karyotypic complexity and heterogeneity found in this analysis (122 statistically significant positive correlations) provide a distinct opportunity to identify agents that are more active against karyotypically complex and chromosomally unstable cancer cells. Such cells would typically be found in the epithelial cancers, which cause so much therapeutic concern and frustration.

Inhibition of Human Papillomavirus Type 16 and 18 E6 and E7 Oncogene Expression by E6 and E7-Specific siRNAs

Zhi-Ming Zheng (NCI).
DHHS Reference No. E–079–2005/0–US–01.
Licensing Contact: Michelle A. Booden; (301) 451–7337; *boodenm@mail.nih.gov*.

Cervical infection with human papillomaviruses (HPVs), such as HPV16 and HPV18, is strongly associated with development of cervical cancer. Integration of the viral genomes into the cervical cell genome is characteristic of infection with these HPVs. Thus, the majority of cervical cancer cells isolated from patients carry these viral genomes and express two viral oncoproteins, E6 and E7, which induce p53 and pRb degradation. Importantly, expression of both E6 and E7 oncogenes is essential for survival of cervical cancer cells.

Small interfering RNA (siRNA) is emerging as a powerful tool for gene silencing and has much potential for anticancer and antiviral applications. The present invention describes a method employing novel siRNA sequences for inhibiting expression of the E6 and E7 viral oncoproteins of HPV 16 and 18, which are required for development and progression of HPV mediated cervical cancer.

Since HPV 16 and HPV 18 are the most prevalent HPV types inducing cervical cancer in women, this discovery may have a significant impact on cervical cancer therapy. This technology could also have additional implications in variety of HPV-associated indications, such as anogenital warts, bladder, and head and neck carcinomas.

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

Biomarkers for Osteoarthritis

Shari M. Ling *et al.* (NIA).
U.S. Provisional Application No. 60/602,334 filed 18 Aug 2004 (DHHS Reference No. E–354–2004/0–US–01).
Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov*.

Osteoarthritis is chronic, often progressive and substantially disabling condition that becomes more common with advanced age. Osteoarthritis commonly involves the knees, hands, hips, neck and back resulting in pain and limitations of movement.

Unfortunately clinically available tests are neither capable of detecting osteoarthritis early in its development, nor sensitive enough to adequately assess disease progression. A better means of diagnosing early osteoarthritis and its progression that can be used to assess the response to therapeutic treatments is needed. The currently available laboratory techniques are highly sensitive but either lack specificity or require large volumes of sample. Rolling Circle Amplification (RCA) is new technology that precisely localizes unique signals arising from single reporter molecules. RCA has been incorporated into antibody-based microarray system protein chips that enable testing with high sensitivity and specificity for hundreds of proteins simultaneously, using small sample volumes.

This invention describes a method of using RCA technology for detecting the expression of serum proteins that are perturbed in osteoarthritis patients. The results of this testing can be used to identify proteins associated with osteoarthritis presence, prediction of osteoarthritis development and prognosis, predict response to osteoarthritis treatment and potentially also identify future anti-osteoarthritic drugs.

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

Water-Soluble, Antineoplastic Derivatives of Taxol

Rudiger D. Haugwitz *et al.* (NCI).
U.S. Patent 4,942,184 issued 17 Jul 1990 (DHHS Reference No. E–090–1987/0–US–01).
Licensing Contact: John Stansberry; 301/435–5236; *stansbej@mail.nih.gov*.

A new class of taxol derivatives offer an improved method for treating certain cancers. The use of taxol as an antineoplastic agent has been limited due to poor solubility in aqueous solutions. These new taxol derivatives have improved water solubility while retaining the cytotoxic properties of the parent compounds. Their method of synthesis and use in treating cancer patients are provided.

Dated: March 7, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–5081 Filed 3–14–05; 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.

SUMMARY: The inventions listed below are owned by an agency of the U.S.