agencies explain their new enforcement policies before that date.

B. Revisions to the Joint FDA–CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

On April 14, 2004, FDA and CBP (we) announced the availability of a joint plan entitled ''Joint FDA–CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes.'' The joint plan describes the process by which FDA and CBP intend to increase integration and examine whether we could amend the timeframe requirements in FDA's prior notice IFR to have the same advanced notice timeframes for arrivals by land via road or rail or arrival via air that are currently in CBP's advance electronic information rule (69 FR 19765). Due to the revisions in the CPG described previously that extend the transition period of the prior notice IFR to November 1, 2004, certain dates outlined in the joint FDA–CBP are revised as follows:

- We intend to implement the plan in November 2004.
- From November 1, 2004, to January 3, 2005, we plan to assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the prior notice IFR (i.e., 2 hours before arrival by land by road; 4 hours before arrival by air or by land by rail; and 8 hours before arrival by water).
- From January 4, 2005, to February 3, 2005, we intend to identify what changes to work practices and staffing would be necessary to determine if FDA could continue to receive, review, and respond to all prior notice submissions with reduced timeframes (e.g., 1 hour or 30 minutes before arrival by land by road; 2 hours before arrival by land by rail; and by ''wheels up'' for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air).
- From February 4, 2005, to May 3, 2005, we plan to implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes.
- In June 2005, we intend to issue a prior notice final rule that responds to the comments we received on the prior notice IFR, including this revised joint plan, during the two open comment periods.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance Reference.'' An electronic version of the revised joint plan is available on the Internet at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

Dated: August 11, 2004.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–18742 Filed 8–12–04; 10:56 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.

Multivariate Profiling of Complex Biological Regulatory Pathways

Kevin Gardner *et al.* (NCI)

U.S. Patent Application No. 10/822,140 filed 12 Apr 2004 (DHHS Reference No. E–127–2003/0–US–02)

Licensing Contact: Cristina Thalhammer-Reyero; (301) 435–4507; *thalhamc@mail.nih.gov.*

This invention is in the general area of methods for high-throughput profiling of transcriptional targets. More particularly, it can be described as systems and methods for generating and analyzing multi-factorial biological response profiles, using a transcriptional approach that profiles the activation of multiple transcriptional targets against combinatorial arrays of signal transducing agents and therapeutic drugs. Cellular behavior in response to changes in its environment is controlled through extracellular events that are biochemically ''transduced'' at the cell membrane, and through a series of molecular signaling pathways converge in the nucleus to influence the combination of transcription factor binding sites that control the activation of targeted genes. Most of those promoter or regulatory regions of gene loci have a modular structure that is bound by two or more different transcriptional factors in a highly cooperative fashion. Accordingly, it is the nature of the surrounding regulatory elements or ''promoter context'' that combine to determine how genes are transcriptionally regulated. Currently there are very few techniques that provide a clear picture of the level of signal integration that must occur at these transcriptional targets.

The technology is further described in *Targeting Combinatorial Transcriptional Complex Assembly at Specific Modules within the Interleukin-2 Promoter* by the *Immunosuppressant SB203580* by James L. Smith, Irene Collins, G. V. R. Chandramouli, Wayne G. Butscher, Elena Zaitseva, Wendy J. Freebern, Cynthia M. Haggerty, Victoria Doseeva, and Kevin Gardner. J. Biol. Chem., Oct 2003; 278: 41034—41046).

Resonant Structure for Spatial and Spectral-Spatial Imaging of Free Radical Spin Probes Using Radiofrequency Time Domain Electron Paramagnetic Resonance Spectroscopy

Nallathamb Devasahayam *et al.* (NCI)

U.S. Patent 6,573,720 issued 03 Jun 2003 (DHHS Reference No. E–166–1997/0–US–07); European, Japanese, Canadian and Australian rights are also pending

Licensing Contact: Michael Shmilovich; (301) 435–5019; shmilovm@mail.nih.gov.

Available for licensing and commercial development is a radio-frequency coil design suitable for detecting time domain electron paramagnetic resonance responses from spin probes after pulsed excitation using radio-frequency irradiation (60–400 MHz). The coil is configured in an array of numerous surface coils of appropriate diameters connected in a parallel configuration with appropriate spacing between individual surface coils to form a volume type resonator. The design can accommodate and irradiate objects of varying dimensions, such as living objects, containing free radical spin probes and induce an EPR signal which can also be recovered by the resonator. Such a resonator has the capability of facilitating the enhanced dissipation of noise to thermal noise levels associated with the input power from the radio-frequency pulse, and recovering weak and rapidly decaying free induction decays. In addition, the lowering of the Q values by over-coupling, instead of resistively damping provides enhanced B1 fields thereby increasing the sensitivity of detection of the resonance signals after pulsed excitation.

Dated: August 2, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–18621 Filed 8–13–04; 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. 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.

Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions

Steven Libutti *et al.* (NCI)
U.S. Provisional Application No. 60/560,900 filed 09 Apr 2004 (DHHS Reference No. E–124–2004/0–US–01)
Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

The present invention is directed to the use of genes differentially expressed in benign and malignant thyroid lesions for the diagnosis and staging of thyroid cancer. The invention allows for the analysis of RNA isolated from tissues using gene expression profiling. The invention has identified a group of genes which can be used as a diagnostic predictor model for differentiating benign versus malignant thyroid tissue using microarray or quantitative RT–PCR.

Pharmacodynamic Assay

Eun Joo Chung and Jane Trepel (NCI)
U.S. Provisional Application No. 60/548,894 filed 27 Feb 2004 (DHHS Reference No. E–094–2004/0–US–01)
Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

This invention is a rapid, simple, sensitive flow cytometric assay for the pharmacodynamic analysis of histone deacetylase inhibitors in clinical development as novel anti-cancer agents. The assay can be performed on 50 microliters of whole blood, the equivalent of a finger stick. The assay can quantify simultaneously the effects of multiple classes of drug and thus be used for pharmacodynamic analysis of HDAC inhibitors in combination therapy.

Adduct Compounds of Pyrrolobenzodiazepinones, Compositions Comprising the Same and Methods Related Thereto

Paul S. Liu (NCI), Gregory Turner, Babu R. Vishnuvajjala (NCI), David Thurston (EM), and Philip W. Howard (EM)
U.S. Provisional Application No. 60/513,751 filed 22 Oct 2003 (DHHS Reference No. E–007–2004/0–US–01)
Licensing Contact: Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov.*

This invention is a small molecule that has potential as a cancer therapeutic, termed SJG–136. It is a dimeric synthetic analog of the pyrrolobenzodiazepine family of anti-tumor antibiotics derived from various *Streptomyces* species. SJG–136 has shown significant cytotoxicity and antitumor activity *in vitro* and *in vivo*. The particular compositions disclosed in the present application represent new structures that were not claimed previously.

Dated: August 6, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–18622 Filed 8–13–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 22–23, 2004.

Open: September 22, 2004, 8:30 a.m. to 12 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: September 23, 2004, 9:45 a.m. to 10:15 a.m.