ARTICLEV11
Duration

Activities under this MOU commence upon signatures of both Participants and continue in effect for a period of five years. The Participants agree to evaluate the agreement during the five-year period. It may be extended or modified by written consent of the Participants. Either Participant, upon 30-days written notice to the other Participant, may terminate this MOU.

Signed at Washington, D.C., in duplicate, this twenty-ninth day of October 2003.

FOR THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

FOR THE CENTRAL SCIENCE LABORATORY
DEPARTMENT OF ENVIRONMENT, FOOD AND RURAL AFFAIRS
OF THE UNITED KINGDOM

Professor M. Roberts
Chief Executive

[FR Doc. 04–15 Filed 1–2–04; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1990D–0194]

Radioimmunoassay Analysis of Hair to Detect the Presence of Drugs of Abuse; Revocation of Compliance Policy Guide 7124.06

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the compliance policy guide (CPG) entitled ''Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06).'' This CPG no longer reflects current agency policy.

DATES: The revocation is effective January 5, 2004.

ADDRESSES: Submit written requests for single copies of CPG 7124.06 to the Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301–827–0482.

A copy of the CPG may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled ''Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06)'' on May 31, 1990. The CPG stated that the use of radioimmunoassay (RIA) to analyze hair for the presence of drugs of abuse lacked scientific evidence of its safety and effectiveness, as defined in 21 CFR 860.7. Accordingly, the CPG indicated that approved premarket approval applications (PMAs) were necessary before commercially distributing these types of devices.

Since publication of this CPG, more than 88 scientific articles on drugs of abuse testing in hair have been published in the peer-reviewed scientific literature. There has been extensive discussion about the analytical performance, the clinical parameters, and sources of error and testing differences for this technology compared to other technologies. FDA has reviewed a number of hair tests and found these to be substantially equivalent to predicate devices measuring drugs of abuse in other matrices. Given these scientific developments and product clearances,

FDA is revoking CPG 7124.06, in its entirety, to eliminate obsolete compliance policy.

Any person who proposes to introduce into commercial distribution an in vitro diagnostic device that is intended to test human hair for drugs of abuse is required to submit a premarket notification (510(k)) to FDA. However, in accordance with § 864.3260 (21 CFR 864.3260), over-the-counter test sample collection systems for drugs of abuse testing (systems sold for use in nonmedical settings such as insurance, workplace, and home) are exempt from the 510(k) submission requirement as long as the laboratory test (whether for urine, hair, or other matrices) has been cleared or approved by FDA, the laboratory is recognized as capable of performing the testing, and the system is properly labeled. (See 21 CFR 809.40 and § 864.3260.)

Dated: December 23, 2003.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–16 Filed 1–2–04; 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.

Combinatorial Therapy for Protein Signaling Diseases

Arpita Mehta (NCI), Lance Liotta (NCI), Emmanuel Petricoin (FDA)

U.S. Provisional Application No. 60/453,629 filed 10 Mar 2003 (DHHS Reference No. E–039–2003/0–US–01)

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

Available for licensing are methods for individualizing therapy based on information obtained concerning deranged signaling pathways that cause disease. The invention includes the use of protein microarrays to detect the deranged signaling pathways that are specific for the subject's disease. The invention covers the use of combination therapy targeting multiple points in the protein network. The invention is based, in part, on the unexpected discovery that treatment of interconnected nodes in a protein signaling pathway can provide a synergistic improvement in therapeutic efficacy at reduced toxicity. For example, a protein signaling network of a diseased cell (*e.g.,* colon cancer) is analyzed and the information obtained from the analysis is used to select at least two drugs whose targets are interconnected within the protein signaling network.

Fluorescent Pteridine Nucleoside Analogs

Mary Hawkins, Wolfgang Pfleiderer, Frank Balis, Michael Davis (NCI)

U.S. Patent 5,525,711 issued 11 Jun 1996 (DHHS Reference No. E–181–1993/0–US–01);

U.S. Patent 5,612,468 issued 18 Mar 1997 (DHHS Reference No. E–181–1993/0–US–23);

U.S. Patent 6,451, 530 issued 17 Sep 2002 (DHHS Reference No. E–155–1996/0–US–03);

U.S. Patent Application No. 09/786,666 filed 07 Mar 2001, allowed (DHHS Reference No. E–035–1998/0–US–0).

Worldwide IP coverage.

Licensing Contact: Susan Carson; 301/435–5020; *carsonsu@mail.nih.gov.*

Pteridines are naturally occurring, highly fluorescent compounds (Quantum yields 0.88–0.40) that are structurally similar to purines and that were first isolated from butterfly wings in 1889. The pteridine nucleoside analogs developed by NCI scientist Hawkins and co-workers are structurally similar to guanosine (3–MI and 6–MI) or adenosine (6–MAP). These analogs are stable, can be formulated as phosphoramidites and are incorporated into oligonucleotides as a direct substitute for a purine base using automated DNA synthesis. The fluorescence properties of these probes are directly impacted by the chemistry of neighboring bases and reflect changes in tertiary structure due to interactions with proteins, RNA or DNA. Even subtle changes in base stacking or base pairing can be observed through changes in fluorescence intensity, lifetimes, energy transfer or anisotropy, making these pteridines ideally suited for the study of DNA/DNA and DNA/protein interactions.

Several applications have been further developed using this technology and one such application causes the pteridine probe to ''bulge'' out of the base stacking environment as it anneals to a target sequence which does not contain a base pairing partner for the pteridine. Prior to binding to the bulge-forming target strand the fluorescence of the probe is very quiet, only ''lighting up'' when bound to a specific sequence. This highly specific technique results in a dramatic increase in fluorescence intensity of up to 27 fold, is very rapid, does not require separation of oligonucleotides in a mixture and has been used in the development of a PCR product detection system. The specific nature of the ''bulge hybridization'' technique may be used to overcome some of the issues caused by non-specific probe binding in standard chip technology. (For a review see: Hawkins, M. (2003) Fluorescent Nucleoside Analogues as DNA Probes, in DNA Technology. J. R. Lakowicz. New York, Kluwer Academic/Plenum Publishers Vol 7 151–175.) More recent applications have shown that the stability and brightness of the guanosine analogy 3–MI are suitable for studies requiring probe detection at the single molecule level and studies using 6–MAP and 2-photon counting excitation demonstrate the adenosine analog's usefulness as a UV probe.

The pteridine nucleoside analogs provide a unique opportunity to use native-like, stable and highly fluorescent probes in the development of further refined, quantitative approaches to the study of DNA/DNA and DNA/protein interactions. The pteridine nucleoside patent portfolio is available for licensing and provides composition and methods of use claims for these versatile fluorophores.

Dated: December 22, 2003.

Steven M. Ferguson,

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

[FR Doc. 04–99 Filed 1–2–04; 8:45 am]

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