

## I. Background

FDA is announcing the availability of a guidance for industry entitled "Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation." This guidance provides recommendations on the information that should be submitted in NDAs and ANDAs for these products, including information on drug product components, manufacturing process, and the associated controls. However, it does not address the manufacture of drug substances. The guidance gives recommendations on information that should be provided to ensure continuing quality and performance characteristics for these drug products. This guidance also provides information on labeling.

In the **Federal Register** of June 2, 1999 (64 FR 29657), FDA announced the availability of a draft version of this guidance. The June 1999 guidance gave interested persons an opportunity to submit comments through August 31, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version. FDA is participating in research relating to these types of drug products through the Product Quality Research Institute (Internet address at <http://www.pqri.org>) and will evaluate whether to update the guidance as information from this research becomes available.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on chemistry, manufacturing, and controls documentation for nasal spray and inhalation solution, suspension, and spray drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 24, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-16797 Filed 7-3-02; 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 agencies 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.

#### Radio Frequency Cauterization Biopsy

*Bradford J. Wood and Christian Pavlovich (CC)*

DHHS Reference Nos. E-207-01/0 filed Oct 17, 2001 and E-207-01/1 filed Apr 08, 2002

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov).

The invention is a method and apparatus for using radio frequency (RF) energy to cauterize the needle track after

percutaneous image-guided needle biopsy using an RF ablation probe. The invention is designed to limit the risks of bleeding and needle track seeding that are inherent risks of any needle biopsy. The device uses a coaxial biopsy arrangement with the outer needle coated with a non-conducting polymer that insulates the needle shaft and the tissue immediately in contact with the shaft. As the needle is pulled back from the organ or tumor target, RF energy is applied to an exposed end portion of the probe, causing cauterization and coagulation of the tissue immediately adjacent to the needle track. A variation on the device could be used to limit bleeding after catheter placement into organs, such as for nephrostomy, biliary drainage, or transhepatic islet cell transplantation.

#### Method and Apparatus for Countercurrent Chromatography

*Yoichiro Ito (NHLBI)*

DHHS Reference No. E-148-01/0 filed Apr 05, 2002

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov).

This invention is an improved column design for High Speed Counter Current Chromatography (HSCCC) that increases partition efficiency by using novel tubing geometries. A standard HSCCC centrifuge uses a multilayer coil as a separation column to produce a high efficiency separation with good retention of the stationary phase in many solvent systems. However, the standard HSCCC, when used for highly viscous, low interfacial solvent systems, is unsuccessful at retaining a suitable amount of the stationary phase. This invention greatly improves efficiency by modifying the column from a coil to spiral geometry. Thereby, this invention creates a centrifugal force gradient, which allows for distribution of the heavier phase in the peripheral and the lighter phase in the proximal part of the column. The effect of the gradient becomes more pronounced as the pitch of the spiral is increased.

#### Method for Segmenting Medical Images and Detecting Surface Anomalies in Anatomical Structures

*Ronald M. Summers et al. (CC)*

U.S. Patent 6,246,784 issued Jun 12, 2001; U.S. Patent 6,345,112 issued Feb 05 2002; Serial No. 10/072,667 filed Feb 05, 2002

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: [berkleyd@od.nih.gov](mailto:berkleyd@od.nih.gov).

The invention is a method for automatically detecting surface anomalies in anatomical structures in virtual colonoscopy and other imaging studies. A region growing method segments three-dimensional image data of an anatomical structure using a tortuous path length limit to constrain voxel growth. The path length limit constrains the number of successive generations of voxel growth from a seed point to prevent leakage of voxels outside the boundary of the anatomical structures. Once segmented, a process for detecting surface anomalies performs a curvature analysis on a computer model of the surface of the structure. This process detects surface anomalies automatically by traversing the vertices in the surface model, computing partial derivatives of the surface at the vertices, and computing curvature characteristics from the partial derivatives. To identify possible anomalies, the process compares the curvature characteristics with predetermined curvature characteristics of anomalies and classifies the vertices. The process further refines potential anomalies by segmenting neighboring vertices that are classified as being part of an anomaly using curvature characteristics. Finally, the process colorizes the anomalies, and computes a camera position and direction for each one to assist the user in viewing 2D rendering of the computer model.

The method may be useful for automated detection of inflammatory, pre-cancerous and cancerous lesions of internal body cavities, such as the colon, airways, blood vessels and bladder. An example of a potential commercial application is as a component of software for clinical interpretation of virtual colonoscopy (CT colonography) examinations.

This research is also described in Summers et al., "Automated Polyp Detection at CT Colonography: Feasibility Assessment in a Human Population," *Radiology* 219:51-59 (2001) and in Summers et al., "Complementary Role of Computer-Aided Detection of Colonic Polyps with CT Colonography," *Radiology*, in press.

Dated: June 24, 2002.

**Jack Spiegel,**

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

[FR Doc. 02-16795 Filed 7-3-02; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center on Minority Health and Health Disparities; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting 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 discussion 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 Center on Minority Health and Health Disparities Special Emphasis Panel, Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training.

*Date:* July 15-17, 2002.

*Time:* 6 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Teresa Chapa, PhD, Chief, Division of Extramural Activities, National Center on Minority Health and Health Disparities, National Institutes of Health, Bethesda, MD 20852, 301/402-1366, [chapat@od.nih.gov](mailto:chapat@od.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: June 26, 2002.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-16793 Filed 7-3-02; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Alcohol Abuse and Alcoholism; Notice of Closed 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 the following meetings.

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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel Fellowship Application.

*Date:* July 16, 2002.

*Time:* 8 am to 6 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Rd, Bethesda, MD 20814.

*Contact Person:* Kathy Ray, Lead Grants Technical Assistant, Extramural Project Review Branch, National Institute of Alcohol Abuse and Alcoholism, National Institutes of Health, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892-7003, 301-443-2932, [klray@mail.nih.gov](mailto:klray@mail.nih.gov).

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel RFA AA02-007—Mutant Mouse Phenotyping: Ethanol-related Behavior and Nervous System Function.

*Date:* July 17, 2002.

*Time:* 1:30 pm to 3:30 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Willco Building, Suite 409, 6000 Executive Boulevard, Rockville, MD 20892, (Telephone Conference Call).

*Contact Person:* Karen P. Peterson, PhD, Scientific Review Administrator, National Institutes of Health, National Institute of Alcohol Abuse and Alcoholism, 6000 Executive Blvd., Suite 409, Bethesda, MD 20892-7003, (301) 451-3883, [kp177z@nih.gov](mailto:kp177z@nih.gov).

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel RFA AA02-006 Non-Human Primate Models of Neurobiological Mechanisms of Adolescent Alcohol Abuse.

*Date:* July 18, 2002.

*Time:* 8 am to 5 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Sandra Camman, Grants Technical Assistant, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Boulevard, Bethesda, MD 20892, 301-443-9419, [scamman@willco.niaaa.nih.gov](mailto:scamman@willco.niaaa.nih.gov).

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel SBIR Contract Topic 023.

*Date:* July 18, 2002.

*Time:* 12:30 pm to 2 pm.

*Agenda:* To review and evaluate contract proposals.

*Place:* Willco Building, Suite 409, 6000 Executive Boulevard, Rockville, MD 20892, (Telephone Conference Call).