Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–27782 Filed 11–5–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 30, 2001.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. Tri-State Financial Services, Inc., Memphis, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Tri-State Bank of Memphis, Memphis, Tennessee.

Board of Governors of the Federal Reserve System, October 31, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–27772 Filed 11–5–01; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0432]

Draft Guidance for Industry on the Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children.'' The Division of Pulmonary and Allergy Drug Products is providing guidance to industry regarding the design, conduct, and evaluation of clinical trials to evaluate the effects of orally inhaled and intranasal corticosteroids on growth in children. This action is important because of recently implemented class labeling of these products with regard to their impact on growth in children. An assessment of the available data supporting the class labeling action has led to recommendations that all drug products of this class be tested by means of a ''growth study.'' The recommendations in this document can provide adequate and well-controlled data that is consistent among drug products and can be included in product labeling.

DATES: Submit written or electronic comments on the draft guidance by February 4, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandy Barnes, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children.'' This draft guidance has been developed by the Division of Pulmonary and Allergy Drug Products, in consultation with the Division of Metabolic and Endocrine Drug Products, to provide guidance in the design, conduct, and evaluation of clinical studies to assess the effects of orally inhaled and intranasal corticosteroids on linear growth.

On July 30 and 31, 1998, the Pulmonary and Allergy Drugs Advisory Committee and the Metabolic and Endocrine Drugs Advisory Committee were jointly convened to discuss the implications of findings in previous clinical studies that indicated that inhaled corticosteroids may, as a class of compounds, affect linear growth in pediatric patients. The joint committees agreed that data were sufficient to justify inclusion of a precautionary statement in the labeling for this class of compounds, but the data were inadequate to precisely determine the decrement in growth velocity resulting from the use of these drug products. Members of the joint committees recommended that companies filing new drug applications for all newly approved corticosteroid products conduct further studies, as post-apptoval phase 4 commitments, to assess the effects of nasally and orally inhaled corticosteroids on growth velocity in prepubertal children.

The draft guidance provides general recommendations for the design and conduct of a ''growth study.'' The Division of Pulmonary and Allergy Drug Products endorses these recommendations to encourage the collection of other evidence that will consistently and accurately describe the effects of intranasal and orally inhaled corticosteroids on growth velocity in children.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the agency's current thinking on evaluating the effects of orally inhaled and intranasal corticosteroids on growth in children. 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 submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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 draft 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 can obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: October 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27756 Filed 11–5–01; 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 contacting Dale D. Berkley, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext. 223; fax: 301/402–0220; e-mail: *berkleyd@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Side Exit Guiding Catheter for Percutaneous Endomyocardial Injection

Robert Lederman (NHLBI)

DHHS Reference No. E–108–01/0 filed 10 Aug 2001

The invention is a device for delivering a therapeutic or diagnostic agent to the heart using a flexible catheter having a non-concentric guide wire to facilitate percutaneous delivery of the catheter across the aortic valve into the left ventricular cavity. The catheter has a side port through which the therapeutic or diagnostic can be delivered and, in particular, by which septal ablation for the treatment of conditions such as hypertrophic cardiomyopathy can be accomplished. This catheter is able to ''turn around'' on itself to treat areas of the myocardium immediately underneath the aortic valve through which the catheter enters. The side port can be used to introduce a needle, laser or radiofrequency probe to perform an endomyocardial ablation procedure.

Methods and Devices for Isolation and Analysis of Cellular Protein Content

Lance A. Liotta, Emmanuel P. Petricoin, Nicole Simone, Michael Emmert-Buck (NCI)

U.S. Patent Application No. 60/120,288 filed February 16, 1999; PCT Application No. PCT/US00/04023 filed February 16, 2000; U.S. Patent Application No. 09/913,667 filed August 16, 2001

The invention is a comprehensive Laser Capture Microdissection (LCM) method for determining protein characteristics of a sample tissue cell to quantitatively discern and compare the protein content of healthy cells versus diseased cells. The tissue source of a tumor metastasis is available from the acquisition of this information. The focus in molecular biology is moving from genomics to proteomics, the study of variations in the protein levels of cells, caused by the state of the cell itself, whether healthy or unhealthy. The invention provides a method for using new and innovative methods for cell analysis. Previous methods, such as UV-laser ablation of unwanted tissue regions and oil well isolation of tissue cells, were complex, labor intensive, and did not utilize protein stabilizers. Direct comparisons between healthy cells and tumor cells were not made due to limitations of the methods. The new method consists of first using the new LCM method to obtain pure cell populations. Next, the sample is placed in a device so that the proteins are solubilized. Then the immunological and biochemical methods and subsequent analyses are performed. These techniques include (but are not limited to) immunoassays, 1D and 2D gel electrophoresis characterization, Western blotting, Matrix Assisted Laser Desorption Ionization/Time of Flight (MALDI/TOF) and Surface Enhanced Laser Desorption Ionization Spectroscopy (SELDI), Protein Arrays and Phosphoprotein Fingerprinting. The methods listed above allow for the direct comparison of both qualitative and quantitative tissue content of healthy and diseased cells, from the same sample. The sequential method of using LCM, protein isolation, analysis and comparison is superior to existing methods because the location of the tumor can be found simply using immunohistochemistry, and protein characteristics, such as amino acid sequence and binding ability can also be discerned. In addition, by using protein fingerprinting, the source of the tumor metastasis is found effectively. The invention has been tested extensively with the different methods listed above. This technology can be used in hospitals and research pathology labs for quantitative measure of protein characteristics of cells.

Isolation of Cellular Material Under Microscopic Visualization

Liotta et al. (NCI)

U.S. Patent 5,843,644 issued December 1, 1998; U.S. Patent 5,843,657 issued December 1, 1998; U.S. Patent 6,010,888 issued January 4, 2000; U.S. Patent 6,204,030 issued March 20, 2001; Serial No. 09/765,937 filed January 18, 2001

This Laser Capture Microdissection (LCM) invention is a method for directly extracting cellular material from a tissue sample using a laser beam to focally activate a special transfer film that bonds specifically to cells identified and targeted by microscopy within the tissue section. The transfer film with the bonded cells is then lifted off the thin tissue section, leaving all unwanted cells (which would contaminate the molecular purity of subsequent analysis) behind. The transparent transfer film is applied to the surface of the tissue section. Under the microscope, the