fee rate are set out in table 1 of this document. For all applications other than premarket notification submissions, the small business rate is 38 percent of the full fee rate. For premarket notification submissions, there is no small business rate in FY 2003. In FY 2004 and subsequent fiscal years, fees for premarket notification submissions will be set so that a small business fee will be 80 percent of a full application fee.

TABLE 1.—FEE TYPES, PERCENT OF PMA FEE, AND FY 2003 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee (percent)	FY 2003 Full Fee (dollars)	FY 2003 Small Business Fee (dollars)
PMA (submitted under section 515(c)(1) or 515(f) of the act or section 351 of the Public Health Service Act (PHS Act))		154,000	58,520
Premarket Report (PMR) (submitted under section 515(c)(2) of the act)	100	154,000	58,520
Panel Track Supplement (to an approved PMA or PMR that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide reasonable assurance of safety and effectiveness)	100	154,000	58,520
Efficacy Supplement (to an approved PMA under section 351 of the PHS Act)	100	154,000	58,520
180-Day Supplement (to an approved PMA or PMR that is not a panel track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling)	21.5	33,110	12,582
Real Time Supplement (to an approved PMA or PMR that is not a panel track supplement and requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement)	7.2	11,088	4,213
Premarket Notification (submitted under section 510(k) of the act)	1.42	2,187	None in FY 2003

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of MDUFMA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379j(h)(4)). No adjustments under this provision are required for fees assessed in FY 2003.

V. Implementation of Fee Collections

A. No Fees May Be Collected Until Enabling Appropriations are Enacted

Under section 738(h) of the act, fees authorized by MDUFMA may neither be collected nor available for obligation unless they are first provided for in appropriation acts. For this reason FDA is not able to accept or deposit any fee revenues until such appropriations are enacted for FY 2003. Therefore, no fees are to be submitted until such appropriations are enacted. After the enactment of enabling appropriations, FDA will publish another notice in the **Federal Register** with detailed payment instructions.

B. Procedures for Firms Seeking to Qualify for Small Business Exemption for First PMA or for Lower Fees for Subsequent Applications.

Firms with gross sales and revenues of $30 million or less, including gross sales and revenues of all affiliate, partner, and parent firms, may qualify for a waiver of the fee for their first PMA, and for lower rates for subsequent PMAs, PMRs, and supplements. Such firms may also qualify for lower rates for premarket notification submissions in FY 2004 and subsequent years. To qualify, these firms will have to submit certified copies of their Federal income tax return for the most recent taxable year, including certified copies of the income tax returns of their affiliate, partner, and parent firms. More detailed procedures for qualifying for small business first-time PMA waiver and lower rates will also be included in the **Federal Register** notice published after the date of enabling appropriations.

C. Subsequent Payment of Fees

Any application or supplement subject to fees under MDUFMA that is submitted after September 30, 2002, is subject to the fee set out in table 1 of this document. FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and 30 days after the date of the **Federal Register** notice the agency will issue after enactment of enabling appropriations. Those invoices will be due and payable within 30 days of issuance. Subsequently, fees must be submitted to FDA at the time that applications are submitted.

Payment, when due, must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of FDA. More complete payment instructions will be included in the **Federal Register** notice published after the date of enabling appropriations.

Dated: November 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–29572 Filed 11–20–02; 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.

Countercurrent Chromatography Separation of Polar Sulfonated Compounds

Adrian Weisz, Yoichiro Ito (NHLBI)

DHHS Reference No. E–304–2002 filed 26 Aug 2002.

Licensing Contact: Dale Berkley; 301/435–5019; *berkleyd@od.nih.gov.*

The invention is a method and apparatus for separating a quantity of a sulfonated polar compound from other compounds in a mixture using countercurrent chromatography. The inventors have found that countercurrent chromatography techniques may be employed to separate different species of polar sulfonated compounds that have resisted isolation in preparative amounts by other chromatographic methods. Countercurrent chromatography is a technique that has been used to separate a variety of compound mixtures, but has not been previously employed to separate multigram quantities of polar sulfonated compounds without use of a ligand. In one embodiment, pH-zone-refining countercurrent chromatography has been found especially successful in this application. It has also been found that the use of an X-type planetary centrifuge is beneficial to obtaining good results. For two particular species of polar sulfonated compounds, the use of a cross-axis (X1.5L-type) centrifuge successfully separated preparative quantities (100 mg, gram, or multi-gram quantities) of material to greater than 99% purity. The cross axis centrifuge facilitated the use of polar solvent systems with high retention of the stationary phase, resulting in successful separation and/or purification of large quantities of polar compounds.

MRI Navigator Methods and Systems

Vinay Pai, Han Wen (NHLBI)

DHHS Reference No. E–164–2002 filed 16 Sep 2002.

Licensing Contact: Dale Berkley; 301/435–5019; *berkleyd@od.nih.gov.*

The invention is a non-breathhold flow sensitive navigator (FLOSEN) technique for reducing respiratory motion artifacts in MR images that tracks the cardiac position using a blood flow based complex difference scheme. The approach tracks the fast moving blood during systole as a marker for the heart position, while stationary or slow moving spins are suppressed. By this approach, the position of the heart can be determined directly, without needing fractional correlation with the diaphragm motion. The method uses a spoiled-Fast Low Angle Shot (FLASH) sequence and incorporates an alternating pair of bipolar velocity-encoding gradients. This method appears to be capable of resolving heart motions greater than +/-0.1 pixel. The navigator based on the position of the fast moving blood volume in the left ventricle may be applied prospectively to shift a subsequent imaging slice to compensate for subject motion, and thereby provide MRI images with increase clarity and resolution.

Method for Functional Kidney Imaging Using Small Dendrimer Contrast Agents

Martin Brechbiel (NCI), Robert Star (NIDDK), Hisataka Kobayashi

DHHS Reference No. E–151–2002 filed 26 Aug 2002.

Licensing Contact: Dale Berkley; 301/435–5019; *berkleyd@od.nih.gov.*

The invention is a method for functional kidney imaging using small dendrimer-based MRI contrast agents that transiently accumulate in renal tubules. The accumulation enables visualization of renal structure and function, permitting assessment of structural and functional damage to the kidneys. Six small dendrimer-based MRI contrast agents have been synthesized, and their pharmacokinetics, whole body retention and renal MRI images were evaluated in mice. Surprisingly, despite having unequal renal clearance properties, all of the dendrimer agents clearly visualized the renal anatomy and proximal straight tubules of the mice better than Gd-[DTPA]-dimeglumine. Dendrimer conjugate contrast agents prepared from PAMAM-G2D, DAB-G3D and DAB-G2D dendrimers were excreted rapidly and may be acceptable for use in clinical applications.

Modified Defensins and Their Use

Dr. Joel Moss et al. (NHLBI)

DHHS Reference No. E–080–2002/0 filed 19 Feb 2002.

Licensing Contact: Marlene Shinn; 301/435–4426; *shinnm@od.nih.gov.*

The ubiquitous use of antibiotics has resulted in the selection of bacteria that are relatively resistant to these drugs. Furthermore, few drugs are effective against viral and fungal microorganisms. There is therefore a continuing need to identify novel agents that reduce or inhibit the growth of such microorganisms, or to identify ways of modifying existing agents in order to give them superior antimicrobial activities, or to identify agents that may recruit inflammatory cells.

Defensins are broad-spectrum antimicrobial molecules that act against infectious agents and play important roles in the innate immune defense in vertebrates. These molecules exhibit a wide range of antimicrobial activities, including cytotoxicity towards bacteria cells, but are also cytotoxic for mammalian cells, which limits their usefulness as antimicrobial agents. The NIH announces the creation of modified defensins through their arginine residues. These compounds can be used to inhibit the toxic effect of defensins, while retaining their T cell chemotactic properties and promoting recruitment of inflammatory cells. In the case of pulmonary disease, these agents can be delivered directly to the site of inflammation by inhalation.

Dated: November 8, 2002.

Jack Spiegel,

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

[FR Doc. 02–29559 Filed 11–20–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other