

regulatory and scientific concerns about inhibitors to Factor VIII, one of the components of blood necessary for clotting, with regard to inhibitor antibodies in Factor VIII products.

**Date and Time:** The workshop will be held on November 21, 2003, from 8 a.m. to 5 p.m.

**Location:** The workshop will be held at Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

**Contact Person:** Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: [wilczek@cber.fda.gov](mailto:wilczek@cber.fda.gov).

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by November 7, 2003. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

**Transcripts:** Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA Web site at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

**SUPPLEMENTARY INFORMATION:** FDA and the International Association for Biologicals (IABs) are co-sponsoring a public workshop on regulatory and scientific concerns pertaining to the potential immunogenicity of Factor VIII products. The purpose of the workshop is to provide a forum for discussion of the inhibitor phenomenon with respect to currently available products and products that are under development by various sponsors. National and international regulatory authorities, manufacturers, clinicians, and academics will discuss their experiences with this issue regarding preclinical testing requirements, the results of clinical trials, and post-marketing surveillance. Other issues to be discussed at the workshop include properties of Factor VIII inhibitor assays, epidemiological aspects of inhibitor formation, and the design of

prospective clinical studies. The public workshop agenda is posted on the FDA Internet at <http://www.fda.gov/cber/meetings/fctrviii112103.htm>.

Dated: October 10, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-26386 Filed 10-17-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

[HRSA-04-030]

#### Amendment to a Notice of Availability of Funds Announced in the HRSA Preview—Primary Health Care Programs: Community and Migrant Health Centers

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Amendment to a Notice of Availability of Funds announced in the HRSA Preview—Primary Health Care Programs: Community and Migrant Health Centers HRSA-04-030.

**SUMMARY:** A Notice of Availability of Funds announced in the HRSA Preview, Primary Health Care Programs: Community and Migrant Health Centers HRSA-04-030, was published in the **Federal Register** on September 4, 2003, (Volume 68, Number 171), FR Doc. 03-22427. On page 52650, under eligibility, the following service areas are added to the list of areas HRSA intends to continue to support health services, given the unmet need inherent in their provisions of services to medically underserved populations. There are no other changes.

#### COMMUNITY/MIGRANT HEALTH CENTERS

City	State	Expiration date
Contact: Jack Egan 301-594-4339		
Hartford .....	CT	1/31/2004
Great Barrington ....	MA	1/31/2004
Salem .....	MA	3/31/2004
Littleton .....	NH	6/30/2004
Middletown .....	CT	6/30/2004
White Plains .....	NY	11/30/2003
Penn Yan .....	NY	12/31/2003
Hatillo .....	PR	1/31/2004
Bronx .....	NY	1/31/2004
Morovis .....	PR	1/31/2004
New York .....	NY	6/30/2004
Baltimore .....	MD	11/30/2003
Contact: Jerri Regan 301-594-4283		

#### COMMUNITY/MIGRANT HEALTH CENTERS—Continued

City	State	Expiration date
Tylertown .....	MS (2)	11/30/2003
Miami .....	FL	1/31/2004
Pompano Beach ....	FL	1/31/2004
Columbia .....	SC	1/31/2004
Manning .....	SC	1/31/2004
Foley .....	AL	2/29/2004
Greensboro .....	GA	2/29/2004
Bowling Green .....	KY	2/29/2004
Russellville .....	AL	6/30/2004
Wilmington .....	NC	6/30/2004
Tallahassee .....	FL	6/30/2004
Contact: Barbara Bailey 301-594-4317		
Houghton Lake .....	MI	12/31/2003
Milwaukee .....	WI	1/31/2004
Muncie .....	IN	2/29/2004
Oak Park .....	IL	5/31/2004
Indianapolis .....	IN	6/30/2004
Contact: Theresa Watkins-Bryant 301-594-4423		
Natchitoches .....	LA	1/31/2004
River Ridge .....	LA	2/29/2004
Baton Rouge .....	LA	5/31/2004
Opelousas .....	LA	6/30/2004
Contact: Jerri Regan 301-594-4283		
St. Louis .....	MO	1/31/2004
Columbia .....	MO	6/30/2004
Contact: Theresa Watkins-Bryant 301-594-4423		
Green Valley .....	AZ	1/31/2004
Los Angeles .....	CA	1/31/2004
Larkspur .....	CA	2/29/2004
Contact: Barbara Bailey 301-594-4317		
Klamath Falls .....	OR	12/31/2003

#### HEALTH CARE FOR THE HOMELESS

City	State	Expiration date
Contact: Jack Egan 301-594-4339		
White Plains .....	NY	11/30/2003
Contact: Jerri Regan 301-594-4283		
Pompano Beach ....	FL	1/31/2004
Contact: Theresa Watkins-Bryant 301-594-4423		
Honolulu .....	HI	10/31/2003
Ventura .....	CA	10/31/2003

#### SCHOOL-BASED HEALTH CENTERS

City	State	Expiration date
Contact: Jack Egan 301-594-4339		
Middletown .....	CT	6/30/2004
Boston .....	MA	8/31/2004
New York .....	NY	6/30/2004

# SCHOOL-BASED HEALTH CENTERS— Continued

City	State	Expiration date
Contact: Jerri Regan 301-594-4283 Wilmington ..... St. Louis .....	NC MO	6/30/2004 1/31/2004

Dated: October 8, 2003.

**Elizabeth M. Duke,**  
Administrator.

[FR Doc. 03-26337 Filed 10-17-03; 8:45 am]

BILLING CODE 4165-15-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, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is 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 application 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 application.

#### Method and Device for Catheter-Based Repair of Cardiac Valves

Robert J. Lederman (NHLBI), U.S. Provisional Application No. 60/426,984 filed 15 Nov 2002 (DHHS Reference No. E-010-2003/0-US-01). Licensing Contact: Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

The invention provides a system and method for catheter-based repair of cardiac valves. The technique may permit non-surgical repair of regurgitant valves using percutaneous catheters in awake patients. The intervention is intended to discontinue/lessen regurgitation of the mitral valve and should provide a viable alternative to the conventional treatment with vasodilator medications and open heart surgery. The technology involves re-apposing of mitral valve leaflets by percutaneous annuloplasty delivering circumferential tensioning devices. Under appropriate imaging guidance (such as fluoroscopic MRI) a circumferential device trajectory is navigated through anatomic (coronary sinus) and non-anatomic spaces to deliver a circumferential tensioning device. As an adjunct, redundant or otherwise disrupted valvar tissue may be oversewn by catheter-based capture, alignment, and suture of valve leaflets. Provided are also designs of various catheters, systems that would be necessary to perform the repair of cardiac valves. Imaging methods, like fluoroscopic (real time MRI), could be used to assist the operator for placement and orientation purposes.

#### Variable Curve Catheter

Robert J. Lederman, Parag Karmarkar (NHLBI), U.S. Provisional Application

No. 60/426,542 filed 15 Nov 2002 (DHHS Reference No. E-035-2003/0-US-01).

Licensing Contact: Michael Shmilovich; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

The invention provides a deflectable tip guiding device, such as a catheter, that enables the operator to vary the radius of curvature of the tip of the catheter. This is a novel variation on the classic "fixed fulcrum" tip deflectors used in minimally invasive procedures in open surgical treatments. The described device would permit more comprehensive ability to navigate complex geometric pathways in patient's body and would enable better access to the target structures (e.g., to all endomyocardial walls from a transaortic approach). The guiding device can be made compatible with imaging methods like MRI. The described technology can be used as a platform for a wide variety of interventional devices for delivery of drugs, cells, energy, or sutures through complex trajectories of the body.

#### Recombinant Plasmids for Soluble Immunoreceptors

Peter Sun (NIAID), DHHS Reference No. E-305-2003/0.

Licensing Contact: Cristina Thalhammer-Reyero; 301/435-4507; [thalhamc@mail.nih.gov](mailto:thalhamc@mail.nih.gov).

Immunoreceptors initiate signals leading to the activation of immune system against invasion pathogens. A number of soluble receptors, representing the extracellular ligand binding domains of the immunoreceptors, have been expressed using a recombinant bacteria expression and reconstitution system. This set of 21 plasmids, which can be used as immunological research reagents or to develop diagnostic tools, comprise the following:

Plasmid	Description
CD16-28b .....	Soluble CD16.
CD94 (S34)-30a .....	Soluble CD94 truncated at S34.
CD94 (E51)-30a .....	Soluble CD94 truncated at E51.
NKG2A (109R)-30a .....	Soluble NKG2A 109R construct.
NKG2A (117G)-30a .....	Soluble NKG2A 117G construct.
TBR1-30a .....	Soluble type II TGF-beta receptor.
C143-30a .....	Soluble KIR2DL2 receptor.
NKG2D-22b .....	Soluble NKG2D receptor.
ULBP-1-22-b .....	Soluble ULBP-1.
ULBP-2-22-b .....	Soluble ULBP-2.
ULBP-3-22b .....	Soluble ULBP-3.
HLA-E-30a .....	Soluble HLA-E heavy chain.
HLA-Cw3 .....	Soluble HLA-Cw3 heavy chain.
TREM-1-22b .....	Soluble TREM-1 receptor.
TREM-2-22b .....	Soluble TREM-2 receptor.
NKp30-22b .....	Soluble NKp30.
NKp46-22b .....	Soluble NKp46.
NKp44-22b .....	Soluble NKp44.