

Dated: December 17, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96-32578 Filed 12-23-96; 8:45 am]

BILLING CODE 4140-01-M

National Heart, Lung, and Blood Institute (NHLBI); Request for Capability Statements From Parties Interested in Collaborating With the NHLBI on the Provision and/or Design of State-of-the-Art Disposable Plasticware Systems for the Collection, Processing, Cryopreservation, Storage, Thawing and Infusion of Umbilical Cord Blood Stem and Progenitor Cells for Transplantation

AGENCY: National Institutes of Health, PHS, NIH.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (NHLBI) is seeking Capability Statements from parties interested in collaborating on a specific aspect of a large, multicenter clinical study. Statements should be focused on the ability to provide state of the art disposable plasticware systems or to design, develop and manufacture a system for the collection, processing, cryopreservation, storage, thawing and infusion of umbilical cord blood stem and progenitor cells for transplantation.

The responding party submit Capability Statements demonstrating previous experience in developing blood collection and processing systems similar to those used for obtaining blood and its components for transfusion. The final system must be a sterile, closed system of disposable plasticware with or without sterile docking capability and containing appropriate processing and cryoprotectant solutions. The system must be produced using good manufacturing practices. It is expected that the responding party will submit the necessary filings with the United States Food and Drug Administration to gain regulatory approval for the system and that there will be coordination with the NHLBI in gaining regulatory approval for all aspects of this study.

This system is to be used in an NHLBI-sponsored multicenter clinical study to determine if stem and progenitor cells from umbilical cord blood units are a clinically acceptable alternative to those from bone marrow or peripheral blood for unrelated-donor allogeneic transplantation. Cord blood banks will be established as part of the study consisting of a total of approximately 15,000 cryopreserved cord bloods units. Collections of cord blood units are planned to begin in the

Spring of 1997. This is not a Request for Proposals (RFP), and responses should not include budgetary information.

Firms responding to this advertisement should provide pertinent information to the requirements mentioned above within thirty (30) days of this publication. The nature and extent of this collaboration and the contractual mechanism under which it will be implemented will be determined based on review of the Capability Statements received.

Capability Statements should be submitted to Dr. Harold T. Safferstein, Technology Development Coordinator, National Heart, Lung, and Blood Institute, Technology Transfer and Commercialization Team, 31 Center Drive, MSC 2490, Bldg. 31/Room 1B32, Bethesda, Maryland 20892-2490, Phone: (301) 402-5579, Fax: (301) 594-3080. E-mail your Capability Statements to: <hs11a@nih.gov>. Capability Statements must be received by the NHLBI on or before January 24, 1997.

Dated: December 16, 1996.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 96-32584 Filed 12-23-96; 8:45 am]

BILLING CODE 4140-01-M

Prospective Grant of Exclusive License: Intra-Urethral Prosthetic Sphincter Valve and Intra-Urethral Valve with Integral Spring

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health (NIH), Department of Health and Human Services, in contemplating the grant of an exclusive license in the United States to practice the invention embodied in U.S. Patent Number 4,553,533 entitled "Intra-Urethral Prosthetic Sphincter Valve" and U.S. Patent Number 5,088,980 to AbbeyMoor Medical, Inc., having a place of business in Minneapolis, Minnesota. The patent rights in this application have been assigned to the United States of America.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The present inventions generally relate to the urologic medical device field of urinary dysfunction. More specifically, these inventions relate to a non-surgically inserted prosthetic valve that will allow patients with urinary dysfunction to void in a substantially normal manner. The valve is fitted with a non-linear spring that avoids false openings at unintended times and does not require undue exertion during urination.

ADDRESSES: Requests for a copy of these patents, inquiries, comments, and other materials relating to the contemplated license should be directed to: John Fahner-Vihtelic, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; Telephone: 301/496-7735 extension 285; Fax: 301/402-0220. Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 24, 1997 will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 11, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96-32579 Filed 12-23-96; 8:45 am]

BILLING CODE 4140-01-M

Prospective Grant of Exclusive License: Gossypol Acetica Acid for the Treatment of Cancer

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health and Human Services, is contemplating the grant of an exclusive world-wide license to practice the inventions embodied in U.S. Patent No. 5,385,936 and U.S. Patent Application No. 08/379,872 to IVAX Corporation of Miami, Florida. U.S. Patent No. 5,385,936 is directed towards a method of treating cancers using Gossypol Acetic Acid (GAA). U.S. Patent Application No. 08/379,872 is directed towards the use of Gossypol for the treatment of cancer. The patent rights in

these inventions have been assigned to the United States of America. This notice revises a previous notice of a prospective grant of exclusive license to Cary Medical Corporation of Great Falls, Virginia for the same technology. See Federal Register, Vol. 61, No. 118, p. 30915-16 (June 18, 1996).

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Gossypol is a biphenolic compound derived from crude cottonseed oil that has been widely used in China as a male contraceptive. Clinical Trials have demonstrated GAA's efficacy against gliomas and adrenal cancer. Clinical trials are planned or underway for the use of GAA in breast and prostate cancer. GAA exhibits low toxicity relative to other chemotherapeutic agents and does not appear to cause myelosuppression, significant hair loss, cardiac failure or neurotoxicity. The milder side effects of the use of GAA include mild fatigue, muscle tremor, dry mouth, dry skin and occasional nausea. Patients treated with GAA, therefore, may be able to continue normal activities.

ADDRESSES: Requests for copies of the issued patent, patent application, inquiries, comments and other materials relating to the contemplated licenses should be directed to: Allan Kiang, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; Telephone: (301) 496-7735 ext. 270; Facsimile: (301) 402-0220. A signed Confidentiality Agreement will be required to receive copies of the patent application. Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before February 24, 1997 will be considered. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 12, 1996.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 96-32581 Filed 12-23-96; 8:45 am]

BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel II in January 1997.

A summary of the meeting may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301)443-4783.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual contract proposals. These discussions could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. The discussion may also reveal information about procurement activities exempt from disclosure by statute and trade secrets and commercial or financial information obtained from a person and privileged and confidential. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c) (3), (4), and (6) and 5 U.S.C. App. 2, § 10(d).

Committee Name: SAMHSA, Special Emphasis Panel II.

Meeting Date: January 7, 1997.

Place: Doubletree Hotel, Woodmont Room, 1750 Rockville Pike, Rockville, MD 20852.

Closed: January 7, 1997 9:00 a.m.-12:00 Noon.

Contact: Katie Baas, Room 17-89, Parklawn Building, Telephone: (301) 443-2437 and FAX: (301) 443-3437.

Dated: December 18, 1996.

Jeri Lipov,

Committee Management Officer, SAMHSA

[FR Doc. 96-32641 Filed 12-23-96; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent to Prepare a National Environmental Policy Act document on the control of invading *Spartina alterniflora* grass on Willapa National Wildlife Refuge and surrounding tidelands of Willapa Bay, Pacific County, WA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Fish and Wildlife Service (FWS) intends to gather information necessary for the preparation of a National Environmental Policy Act (NEPA) document for the control of invading *Spartina alterniflora* grass on Willapa National Wildlife Refuge and surrounding tidelands of Willapa Bay, Pacific County, Washington. Public scoping meetings to solicit comments from all interested parties regarding the scope and content of the NEPA document will also be held. This notice is being furnished pursuant to the National Environmental Policy Act, implementing regulations, and FWS policy to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the document. Comments and participation in this scoping process are solicited.

SCOPING MEETINGS: Public scoping meetings will be held from 7:00 p.m. to 9:00 p.m. at the Raymond Community Center (323 Third Street, Raymond, WA) on January 6, 1997, and from 7:00 p.m. to 9:00 p.m. at the Peninsula Church Center (5000 N. Street, Seaview, WA) on January 7, 1997. Interested agencies, organizations, and individuals are encouraged to attend either of the scoping meetings to identify and discuss major issues, concerns, and opportunities that should be addressed in the NEPA Document. Interested parties are reminded that the primary purpose of the scoping process is to identify, rather than debate the significant issues related to the proposed action. In order to insure that all issues are correctly and completely recorded and considered, those persons providing oral presentations at the scoping meetings are encouraged to provide agency representatives with a written statement to more fully explain their remarks.

FOR FURTHER INFORMATION CONTACT: James A. Hidy, Refuge Manager Willapa National Wildlife Refuge, HC 01 Box