

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2010-N-0550]

Compliance Policy Guide Sec. 390.500 Definition of “High-Voltage Vacuum Switch”—21 CFR 1002.61(a)(3) and (b)(2); Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 390.500 Definition of “High-Voltage Vacuum Switch”—21 CFR 1002.61(a)(3) and (b)(2) (CPG Sec. 390.500). CPG Sec. 390.500 is included in FDA’s Compliance Policy Guides Manual, which was listed in the Annual Comprehensive List of Guidance Documents that published on August 9, 2010.

DATES: The withdrawal is effective December 7, 2010.

FOR FURTHER INFORMATION CONTACT:

Sean M. Boyd, Center for Devices and Radiological Health, Office of Communication, Education, and Radiological Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4640, Silver Spring, MD 20993-0002, 301-796-5895.

SUPPLEMENTARY INFORMATION: In a notice containing a cumulative list of guidances available from the agency that published in the **Federal Register** of August 9, 2010 (75 FR 48180 at 48233), FDA included the Compliance Policy Guides Manual, which includes CPG Sec. 390.500. FDA is withdrawing CPG Sec. 390.500 because it is obsolete.

Dated: November 22, 2010.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010-30677 Filed 12-6-10; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering NACBIB January 2011.

Date: January 24, 2011.

Open: 8:30 a.m. to 1 p.m.

Agenda: Report from the Institute Director, other Institute Staff and discussion of strategic plan.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

Closed: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

Contact Person: Anthony Demsey, PhD, Director, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute’s/Center’s home page: <http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm>, where an agenda and any additional information for the meeting will be posted when available.

Dated: December 1, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-30644 Filed 12-6-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 USC, as amended. The grant applications and/or contract Proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: February 4, 2011.

Closed: February 4, 2011, 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Open: February 4, 2011, 11 a.m. to 4 p.m.

Agenda: Opening remarks by the Director of the National Center for Complementary and Alternative Medicine, presentation of a new research initiative, and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, PhD, Executive Secretary, Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892. (301) 594-2014.

The public comments session is scheduled from 3:30 to 4 p.m. on February 4, 2011, but could change depending on the actual time spent on each agenda item. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of

organizations are requested to notify Dr. Martin H. Goldrosen, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301-594-2014, Fax: 301-480-9970. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 p.m. on January 26, 2011. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Martin H. Goldrosen at the address listed above up to ten calendar days (February 14, 2011) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Martin H. Goldrosen, Executive Secretary, NACCAM, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301-594-2014, Fax 301-480-9970, or via e-mail at naccames@mail.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: nccam.nih.gov/about/naccam, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.701, ARRA Related Biomedical Research and Research Support Awards; 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: November 30, 2010.

Jennifer S. Spaeth,
Director, Office of Federal Advisory
Committee Policy.

[FR Doc. 2010-30641 Filed 12-6-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Devices for Treating Dysphagia and Dysphonia

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice.

SUMMARY: This is 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 (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive worldwide license to practice the invention embodied in: HHS Ref. No. E-251-2005/0,1,1/2:

Patent/application number	Territory	Filing date	Status
60/695,424	US	July 1, 2005	Expired.
60/787,215	US	March 30, 2006	Expired.
PCT/US2006/025535	Intl	June 30, 2006	Expired.
PCT/US2007/007993	Intl	March 20, 2007	Expired.
PCT/US2009/57158	Intl	September 16, 2009	Expired.
2006265985	AU	December 18, 2007	Pending.
2,614,072	CA	June 30, 2006	Pending.
06785933.0	EP	June 30, 2006	Pending.
2008-520302	JP	June 30, 2006	Pending.
11/993,094	US	December 19, 2007	Pending.
08112281.5	HK	November 5, 2008	Pending.
12/240,398	US	September 29, 2008	Pending.
12/211,633	US	September 16, 2008	Pending.

to Passy-Muir, Inc., a company incorporated under the laws of the State of California having its headquarters in Irvine, California. The United States of America is the assignee of the rights of the above inventions. The contemplated exclusive license may be granted in a field of use limited to devices for treating dysphagia and dysphonia.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before January 6, 2011 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail:

shmilovm@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The patents and patent applications intended for licensure disclose or cover a system, device and method for rehabilitating dysphagia due to stroke, ex-tubation or coronary bypass surgery. Swallowing recovery alleviates the risk of aspiration by augmenting volitional control using a simultaneous motor act (e.g., such as pressing a button to indicate when they are ready to swallow). It is believed that such motor training also initiates sensory stimulation, immediately preceding the motor act and that such sensory stimulation enhances excitation of a central pattern generator in the brain stem that augments the volitional

control of swallowing. This principle is applicable to other neurological impairments; their associated enhancement of voluntary motor act control by the patient initiating immediately concurrent and related sensory stimulations. Neurological impairments that are contemplated include reflex actions involving interactions between afferent and efferent paths (at the spinal cord or in the brain stem) as well as higher order interactions. This invention includes methods for treating neurologically impaired humans using devices such as those that produce vibratory stimulation, pressure stimulation, auditory stimulation, temperature stimulation, visual stimulation, olfactory stimulation, taste stimulation, or a combination of these. Upon activation a vibrator moves and vibrates the larynx. Patients can initiate sensory stimulation immediately prior to the patient's own initiation of a swallow.