

or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

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 reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.

Date: September 14–15, 2010.

Time: September 14, 2010, 8:30 a.m. to 5:30 p.m.

Agenda: The focus of this meeting will be on the deliberations of the Translational Medicine and Therapeutics working group and its respective stakeholder consultation. Presentation and discussion will include, but is not limited to, representatives from academia, government, industry, venture capital firms, and patient advocacy groups. Additional presentation and discussion will include recommendations from the Substance Use, Abuse and Addiction working group and the Intramural Research Program working group. Time will be allotted both days for presentation and discussion of each Working Group's recommendations. Any supporting documentation for this meeting, including the agenda, will be available at <http://smrb.od.nih.gov>. Sign up for public comment will begin at approximately 7:30 a.m. on both September 14 and 15 and will be restricted to one sign in per person. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person's address below.

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

Time: September 15, 2010, 8 a.m. to 5 p.m.

Agenda: Continuation of September 14th meeting.

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

Contact Person: Lyric Jorgenson, Health Sciences Policy Analyst Office of Science Policy, Office of the Director, NIH, National Institutes of Health, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496-6837.

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.

The meeting will also be webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, will be available at <http://smrb.od.nih.gov>.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, 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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 16, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0423]

ASK (Assess Specific Kinds of CHILDREN Challenges for Neurologic Devices) Study Children Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ASK (Assess Specific Kinds of CHILDREN Challenges for Neurologic Devices) Study Children Workshop. The purpose of the public workshop is to solicit comments from academic investigators and clinicians associated with the use, research and/or development of pediatric neuroprostheses regarding approaches for enhancing the protection and promotion of public health in children and adolescents with neuroprostheses. The public workshop will provide an

overview of pediatric initiatives across the Agency, neurological and neurosurgical perspectives on medical devices, a review of pediatric assessments and outcome measures, and scientific research issues associated with the use of neuroprostheses in pediatric populations, including cochlear implants, deep brain stimulators, hydrocephalus shunts, spinal cord stimulators, and vagus nerve stimulators. Information from this public workshop will help establish a science-based framework of recommendations to aid in the development of more efficient strategies in evaluating pediatric neuroprostheses regulated by the Agency.

Dates and Time: The public workshop will be held on September 13, 2010, from 9 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, rm. 1503, Silver Spring, MD 20993. For lodging and directions, please refer to the meeting on the Internet at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

Contact Person: Carlos Peña, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4264, Silver Spring, MD 20993-0002, 301-796-8521, FAX: 301-847-8617, email: carlos.pena@fda.hhs.gov.

Registration: Registration requests must be received by 5 p.m. on September 6, 2010. If you wish to attend the public meeting, you must register online at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

If you wish to make an oral presentation at the workshop, you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you wish to make an oral presentation during the open comment period at the workshop, you must indicate this at the time of registration. FDA requests that presentations focus on the areas described in this notice. You should also identify which discussion topic you wish to address in

your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak.

If you need special accommodations due to a disability (such as wheelchair access or a sign language interpreter), please notify Carlos Peña, at least 7 days in advance of the meeting.

Comments: FDA is holding this public workshop to obtain information about children and adolescents with neuroprostheses. The deadline for submitting comments regarding this public workshop is September 6, 2010.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to solicit information from academic investigators and clinicians associated with the use, research and/or development of pediatric neuroprostheses regarding approaches for enhancing the protection and promotion of public health in children and adolescents with neuroprostheses. Information from this public workshop will help establish a science-based framework of recommendations to aid in the development of more efficient strategies in evaluating pediatric neuroprostheses regulated by the Agency.

The Agency seeks discussion with interested parties regarding the use of neuroprostheses in pediatric populations. The public workshop will provide an overview of pediatric initiatives across the Agency, neurological and neurosurgical perspectives on medical devices, a review of pediatric assessments and outcome measures, and scientific

research issues associated with the use of neuroprostheses in pediatric populations, including cochlear implants, deep brain stimulators, hydrocephalus shunts, spinal cord stimulators, and vagus nerve stimulators.

Since the Food and Drug Administration Amendments Act of 2007 was signed into law, there has been increased interest in stimulating scientifically sound clinical research related to pediatric populations. However, to date, none of the initiatives has focused specifically on neuroprosthetic devices for pediatric patients. It is hoped that this meeting will provide a forum for open discussion and information exchange among interested parties, FDA, and other stakeholders to lay a framework for establishing a science-based framework of recommendations to aid in the development of more efficient strategies in evaluating pediatric neuroprostheses regulated by the Agency and stimulating further research into the use of devices to treat disorders and diseases that affect pediatric patients.

II. What Will Be the Format for the Meeting?

The format for the meeting will include general sessions in the morning and the afternoon. Invited expert speakers will present information to stimulate thought regarding current needs and concerns regarding neuroprosthetic devices that involve pediatric patients. Presentations will be followed by a focused, moderated comment session.

III. What Are the General Topic Areas We Intend To Address at the Public Workshop?

We hope to discuss the following topics:

- Pediatric initiatives across the Agency
- The ASK Children Study
- Clinical perspectives
- Patient and advocacy group perspectives
- Science and research perspectives

The workshop will conclude with an overall open discussion that will cover the workshop purposes and questions, areas of cooperation, next steps, and future directions.

IV. What Are the Issues That Will Be Discussed and Considered?

Issues regarding the research and/or development of pediatric neuroprostheses, current clinical use, and approaches for enhancing the protection and promotion of public

health in children and adolescents with neuroprostheses will be discussed and considered.

V. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

Dated: August 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Published Privacy Impact Assessments on the Web

AGENCY: Privacy Office, DHS.

ACTION: Notice of publication of Privacy Impact Assessments.

SUMMARY: The Privacy Office of the Department of Homeland Security (DHS) is making available thirty-five Privacy Impact Assessments on various programs and systems in the Department. These assessments were approved and published on the Privacy Office's Web site between October 1, 2009 and May 31, 2010.

DATES: The Privacy Impact Assessments will be available on the DHS Web site until October 19, 2010, after which they may be obtained by contacting the DHS Privacy Office (contact information below).

FOR FURTHER INFORMATION CONTACT: Mary Ellen Callahan, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528, or e-mail: pia@dhs.gov.

SUPPLEMENTARY INFORMATION: Between October 1, 2009, and May 31, 2010, the