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

U.S. Food & Drug Administration

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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 neuroprotheses 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 [1].
Contact Person: Carlos Pe[ntilde]a, 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 [2].
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 [1]. 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

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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 Pe[ntilde]a, 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 [4]. 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 neuroprotheses 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 [1].
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 [1].

Dated: August 16, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010-20659 Filed 8-19-10; 8:45 am]
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request-comments?qt-video_of_the_day=0&qt-recent_content=0

Links:
[1] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm
[2] mailto://edocket.access.gpo.gov/2010/carlos.pena@fda.hhs.gov
[3] http://www.mdtmag.com/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=11708
[4] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
[5] http://edocket.access.gpo.gov/2010/2010-20659.htm