

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Tuesday, December 8, 2009, from 8 a.m. to 6 p.m.

Location: Hilton, Washington, DC/Rockville Executive Meeting Center, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Doreen Kezer, Office of Medical and Scientific Programs (HF-33), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1249, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 8, 2009, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, for Abilify (aripiprazole), Argatroban (argatroban), Orencia (abatacept), Humira (adalimumab), Zemuron (rocuronium bromide), Cancidas (caspofungin acetate), Cardiolite (technetium Tc99 sestamibi), Evicel—fibrin sealant (human), Artiss—fibrin sealant (human), Voluven—6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection, Reyataz (atazanavir sulfate), Kaletra (lopinavir/ritonavir), Aptivus (tipranavir), Zetia (ezetimibe), Vytorin (ezetimibe/simvastatin), Ventolin HFA (albuterol sulfate). The committee will also receive a brief update on atypical antipsychotic drugs as requested by the Pediatric Advisory Committee Meeting on November 18, 2008.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is

available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before Tuesday, November 24, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before Monday, November 16, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by Tuesday, November 17, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Doreen Kezer at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 1, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-24013 Filed 10-5-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Director's Council of Public Representatives.

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: Director's Council of Public Representatives.

Date: October 30, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: Key topics for this meeting will focus on emerging issues of public importance in biomedical and behavioral research. Further information will be available on the COPR Web site.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20852.

Contact Person: Kelli L. Carrington Executive Secretary/Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, 301-594-4575, carringk@mail.nih.gov.

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.

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: <http://www.copr.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(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: September 28, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-23800 Filed 10-5-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: November 2, 2009, 8:30 a.m. to 5 p.m.; November 3, 2009, 8:30 a.m. to 5 p.m.

Place: Hilton Hotel, 1750 Rockville Pike, Rockville, Maryland 20852, Telephone: (301) 468-1100, Fax: (301) 468-0308.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

Agenda items are subject to change as priorities indicate.

FOR FURTHER INFORMATION CONTACT: Gladys Cate, Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 594-0367.

Dated: September 29, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-24045 Filed 10-5-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 4, 2009, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Ronald P. Jean, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301-796-5650, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 4, 2009, the committee will discuss, make recommendations and vote on a premarket approval application for the Dynesys Spinal System, sponsored by Zimmer Spine. The Dynesys Spinal System is indicated to provide spinal alignment and stabilization in skeletally mature patients at one or two contiguous levels from L1-S1.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will

be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available on the FDA Internet under the appropriate date at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 28, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 20, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 21, 2009.

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FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ann Marie Williams, Conference Management Staff, 301-796-5966, at least 7 days in advance of the meeting.

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