

In addition, the NSF risk appears to vary among the GBCAs. Postmarketing data and corroborating preclinical data that demonstrated a significant, unacceptable NSF risk has led FDA to recently contraindicate Omniscan, Magnevist, and Optimark for patients with acute kidney injury and severe chronic renal failure. The risk of NSF associated with the remaining marketed GBCAs for patients with these kidney conditions is expected to be lower, but is not fully understood. Therefore, there is a public health need to study the risk of NSF associated with the exposure of those remaining marketed GBCAs and to inform the development of reliable knowledge, practice guidelines, and regulatory processes in relationship to the safety of these agents.

B. Research Objectives

The primary goal of this project is to employ an existing Quality Assurance (QA) registry of patients with renal failure who received GBCAs as the basis for a prospective registry study of the risk of NSF associated with GBCAs among renal patients. Patients already enrolled in this QA registry will be invited to enroll in an outpatient registry to study their risk of NSF. Data from this project will help understand the effect of cumulative dosing of the GBCAs in patients with slow deterioration of renal function as occurs with aging, and the data might also provide further reassurance as to the safety of the GBCAs identified as having minimal association with the risk of NSF by prospectively following patients who have received GBCAs. In addition, the project will also provide data on the occurrence of allergic reactions associated with the GBCA administration. A recent report by Prince suggests an increased risk of allergic reactions with MultiHance (Ref. 3).

The prospective design of this project is important since most previous clinical investigations have been based on chart review or other retrospective data. Implementation of this project may also provide the structure for future prospective investigations of other diseases with an acute phase of hospitalization superimposed on a chronic course.

C. Eligibility Information

This is a sole source cooperative agreement to: University of Pittsburgh Medical Center.

II. Award Information/Funds Available

A. Award Amount

CDER anticipates providing in FY2012 \$250,000 (total costs include direct and indirect costs), for one award subject to availability of funds in support of this project.

B. Length of Support

Support will be 1 year with the possibility of an additional year of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and subject to the availability of Fiscal Year appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM311309.pdf>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Persons interested in applying for a grant may obtain an application at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM311309.pdf>. For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons Steps 1 and 2, in detail, can be found at: http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at: <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit one paper application to: Vieda Hubbard, Grants Management, Food and Drug Administration, Division of Support and Grants, 5630 Fishers Lane, rm. 1079, HFA 500, Rockville, MD 20857 and a copy to Ira Krefting, Center for Drug Evaluation and Research, Division of Medical Imaging Products, 10903 New Hampshire Ave. Bldg. 22, Rm. 2100, Silver Spring, MD 20993.

IV. References

The following references have been placed on display in the Division of

Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Marckmann, Peter; Skov, Lone; Rossen, Kristian; Dupont, Anders; Damholt, Mette Brimnes; Heaf, James Goya; and Thomsen, Henrik, *Journal of the American Society of Nephrology*, 17:2359, 2006.

2. Wang, Yingbing; Alkasab, Tarik; Narin, Ozden; Nazarian, Rosalynn; Kaewali, Rathachai, Kaewlai; Kay, Jonathan; and Abujudeh, Hani, *Radiology*, 260:105, 2011.

3. Prince, Martin; Zhang, Honglei; Zou, Zhitong; Staron, Ronald; and Brill, Paula, *American Journal of Radiology*, 196(2):W138, 2011.

Dated: July 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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 September 21, 2012 from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Sara J. Anderson, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg 66, rm. 1611, Silver Spring, MD 20993-0002, 301 796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA

advisory committee information. 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 21, 2012, the committee will discuss and make recommendations regarding the classification of posterior cervical screws, including pedicle and lateral mass screws. Cervical pedicle and lateral mass screws are components of rigid, posterior spinal screw and rod systems generally intended as an adjunct to fusion for the treatment of degenerative disc disease (as defined by neck pain confirmed by radiographic studies), trauma, deformity, failed previous fusion, tumor, infection, and inflammatory disorders in the cervical spine.

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 meeting 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 September 14, 2012. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 1:15 p.m. on September 21, 2012. Those individuals interested in making 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 September 6, 2012. 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 September 7, 2012.

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 James Clark at James.Clark@fda.hhs.gov or 301-796-5293 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: June 12, 2012.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 September 19, 2012, between approximately 8 a.m. and 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at: <https://collaboration.fda.gov/vrbpac/>.

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 19, 2012, the committee will meet in open session to discuss consideration of the appropriateness of cell lines derived from human tumors for vaccine manufacture.

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 meeting link.