

performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection. *Title of Information Collection:* Deficiencies and Plan of Correction (CMS-2567) and Supporting Regulations contained in 42 CFR 488.18, 488.26, and 488.28. *Use:* Section 1864(a) of the Social Security Act requires that the Secretary use State survey agencies to conduct surveys to determine whether health care facilities meet Medicare and Clinical Laboratory Improvement Amendments participation requirements. The CMS-2567 form is the means by which the survey findings are documented. This section of the law further requires that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The CMS-2567 form is the vehicle for this disclosure. The regulations at 42 CFR 488.18 require that State survey agencies document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS-2567. 42 CFR 488.26 and 488.28 further delineate how compliance findings must be recorded and that CMS prescribed forms must be used.

The form is also used by health care facilities to document their plan of correction and by CMS, the States, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance.

*Form Number:* CMS-2567 (OCN 0938-0391). *Frequency:* Yearly and occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 62,000. *Total Annual Responses:* 62,000. *Total Annual Hours:* 134,540. (For policy questions regarding this collection contact Angela Mason-Elbert at 410-786-8279. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *September 17, 2012*.

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 12, 2012.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2012-17378 Filed 7-17-12; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0011]

#### Establish a Patient-Based Registry To Evaluate the Association of Gadolinium Based Contrast Agents Exposure and Nephrogenic Systemic Fibrosis

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the development of a patient-based registry to evaluate the association of gadolinium based contrast agents (GBCAs) exposure and nephrogenic systemic fibrosis (NSF). The goal of the GBCA project is to study the safety of the GBCAs when used as indicated.

**DATES:** Important dates are as follows:

1. The application due date is August 1, 2012.
2. The anticipated start date is September 13, 2012.
3. The opening date is July 2, 2012.
4. The expiration date is August 2, 2012.

**ADDRESSES:** Submit the paper application to: Vieda Hubbard, Grants

Management (HFA-500), 5630 Fishers Lane, 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. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

#### FOR FURTHER INFORMATION AND

**ADDITIONAL REQUIREMENTS CONTACT:** Ira Krefting, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993, 301-796-1135, Email: [ira.krefting@fda.hhs.gov](mailto:ira.krefting@fda.hhs.gov); or Vieda Hubbard, Office of Acquisitions and Grants Services (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2034, Rockville, MD 20857, 301-827-7177, Email: [vieda.hubbard@fda.hhs.gov](mailto:vieda.hubbard@fda.hhs.gov).

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM311309.pdf>.

#### SUPPLEMENTARY INFORMATION:

##### I. Funding Opportunity Description

RFA-FD-12-029  
93.103

##### A. Background

Annually, millions of patients undergo magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) procedures employing GBCAs. Postmarketing data indicate that six of the eight GBCAs approved for use in the United States have been directly implicated in the development of NSF, a newly characterized, potentially fatal systemic fibrotic skin and internal organ condition. Among the factors that may increase the risk for NSF are repeated or higher than recommended doses of GBCA and degree of renal impairment at the time of exposure; imaging patients with severe renal failure appear to be at highest risk. In one, early retrospective study of 370 patients with severe renal failure who received gadodiamide the estimated risk for development of NSF was 4 percent (Ref. 1). In a recent retrospective chart review study by Wang of 52,954 contrast MR examinations with restrictive guidelines for GBCA in patients with renal failure no new cases of NSF were found (Ref. 2).

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 Pittsburg 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](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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**BILLING CODE 4160-01-P**

## 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