

letter. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. The nominee's contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 14, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-00964 Filed 1-17-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1633]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of nonvoting industry representatives to serve on the Medical Devices Advisory Committee (MDAC) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in

the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA (see **ADDRESSES**) by February 20, 2014, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by February 20, 2014.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5234, Silver Spring, MD 20993. Telephone: 301-796-5960, Fax: 301-847-8505, email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry. The Agency is requesting nominations for nonvoting industry representatives to certain panels identified in the following paragraphs.

I. Functions of MDAC

(1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the FD&C Act; (8) advise on the necessity to ban a device; (9) respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10)

make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

A. Dental Products Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics, or bone physiology relative to the oral and maxillofacial area and makes appropriate recommendations to the Commissioner.

B. Hematology and Pathology Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including pathology, hematology, histopathology, cytotechnology, and molecular biology and makes appropriate recommendations to the Commissioner.

C. Immunology Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including oncology, immunology, and allergy and makes appropriate recommendations to the Commissioner.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not

bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the panel. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 13, 2014.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission For OMB Review; 30-Day Comment Request: Gulf Long-Term Follow-Up Study (GuLF STUDY)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health

Sciences (NIEHS), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 7, 2013 on pages 66945–66946 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3–05, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number 919–541–4668 or Email your request, including your address to: *Sandler@niehs.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Gulf Long-Term Follow-Up Study (GuLF STUDY), 0925–0626, Expiration Date 01/31/2014—REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection:

The purpose of the GuLF STUDY is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures related to the Deepwater Horizon disaster, and to create a resource for additional collaborative research on focused hypotheses or subgroups. Exposures range from negligible to potentially significant; however, potential long-term human health consequences are largely unknown due to insufficient research in this area.

The study has enrolled 32,762 participants with a range of jobs/exposures, including participants who performed various types of clean-up-related work (“exposed”) and other who did not (“unexposed” controls). Of the 32,762 enrolled into the Full Cohort, 20,000 have been assigned to the Active Follow-up Sub-cohort, and 6,000 of these have been assigned to the Biomedical Surveillance Sub-cohort.

In order to minimize loss to follow-up, updated contact information will be collected yearly for the Full Cohort. Follow-up questionnaires will be administered biennially to the Active Follow-up Sub-Cohort to assess changes in health status and factors that could confound associations between exposures and outcomes. A supplemental mental health questionnaire will be administered repeatedly over a 2-year period to a subset of 4,600 participants in the Active Follow-up Sub-cohort to assess mental health trajectories among those affected by the oil spill and utilization of mental health services in the Gulf region. Participants in the Biomedical Surveillance Sub-cohort will be invited to take part in a comprehensive research-based clinical examination. The clinical exam provides an opportunity to carry out more comprehensive clinical testing and mental health evaluations than could be completed during the baseline home visit. The exams will allow for a much more in-depth assessment of pulmonary, neurological, and mental health outcomes that may be associated with the Deepwater Horizon oil spill exposures and experiences.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 21,724.