accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: October 26, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–28244 Filed 10–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0238]

Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice, published in the **Federal Register** of May 23, 2011 (76 FR 29767), entitled ''Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Request for Comments.'' In that document, FDA opened a docket and requested information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by December 20, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, (240) 402–2166; or Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–9207.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 23, 2011 (76 FR 29767), FDA published a notice with a 90-day comment period to obtain information about preventive controls and other practices used by facilities to identify and address hazards associated with specific types of food and specific processes. Information obtained will assist FDA in the development of guidance on preventive controls for food facilities that manufacture, process, pack, or hold human food or animal food/feed (including pet food).

The Agency has received a request for an extension of the comment period for this notice. FDA has considered the request and is extending the comment period for the notice entitled ''Preventive Controls for Registered Human Food and Animal Food/Feed Facilities; Request for Comments'' until December 20, 2011. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

Dated: October 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28239 Filed 10–31–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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 organizations interested in participating in the selection of nonvoting industry representatives to serve on certain device panels of 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 a nonvoting industry representative(s) 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 current vacancies effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by December 1, 2011, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by December 1, 2011.

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, (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. Clinical Chemistry and Clinical Toxicology 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 clinical toxicology, clinical chemistry, endocrinology, and oncology, and makes appropriate recommendations to the Commissioner.

B. Ear, Nose, and Throat Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of market and investigational ear, nose, and throat devices, and makes appropriate recommendations to the Commissioner.

C. Medical Devices Dispute Resolution Panel

Provides advice to the Center Director on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to Agency decisions or actions.

D. Microbiology 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 microbiology, virology, and infectious disease, and makes appropriate recommendations to the Commissioner.

E. Molecular and Clinical Genetics 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 clinical and molecular genetics, and makes appropriate recommendations to the Commissioner.

F. Orthopaedic and Rehabilitation Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopaedic and rehabilitation devices, and makes appropriate recommendations to the Commissioner.

G. Radiological Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational diagnostic or therapeutic radiological and nuclear medicine devices 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 resumes. 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 has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees and, therefore, encourages nominations for 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: October 26, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–28224 Filed 10–31–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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 the National Mammography Quality Assurance Advisory Committees

AGENCY: Food and Drug Administration, HHS.