FOR FURTHER INFORMATION CONTACT: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3638.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket) into class II (special controls). In the same issue of the **Federal Register** (71 FR 63774), FDA published a notice of availability of a draft guidance document entitled ''Class II Special Controls Guidance Document: Absorbable Hemostatic Device.'' FDA invited interested persons to comment on the draft guidance document by January 29, 2007. In the **Federal Register** of May 8, 2007 (72 FR 26134), FDA published a notice reopening the comment period for 30 days.

On July 2, 2007, FDA received a petition under 21 CFR 10.30 and 10.35 requesting that the agency refrain from issuing a final regulation for the proposed reclassification and the draft special controls guidance for the absorbable hemostatic device until an updated and complete administrative record is made available to the public. The petitioner also requested that FDA reopen the rulemaking for the proposed reclassification to allow submission of comments based on the administrative record. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on the proposed rule for 30 days. Because the issues presented by the guidance document are intertwined with those presented by the proposed rule, FDA is reopening the comment period on the guidance document for the same period.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled ''Class II Specials Controls Document: Absorbable Hemostatic Device,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1558 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers'' addresses), small manufacturer'' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

III. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments submissions will be accepted by FDA through FDMS only.

Dated: September 4, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21197 Filed 9–10–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0475]

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

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 Devices Good Manufacturing Practice Advisory Committee (DGMPAC) and certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health notify FDA in writing. 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 October 14, 2008, for the vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by October 14, 2008.

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 7520 Standish Pl. (MPN1), Rockville, MD 20855, 240–276–8938, e-mail: *kathleen.walker@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The agency intends to add nonvoting industry representatives to the following advisory committees:

I. CDRH—Various Committees and Panels

A. Devices Good Manufacturing Practice Advisory Committee (DGMPAC)

Section 520 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(j)), as amended, provides that the DGMPAC shall be composed of two representatives of interests of the device manufacturing industry.

B. Medical Devices Advisory Committee

Section 520(f)(3) of the act, 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.

II. CDRH—Committee and Panels Functions

FDA is requesting nominations for nonvoting members representing industry interests for the following vacancies listed in table 1 of this document.

TABLE 1.

Committee Name or Panel	Approximate Date Needed
DGMPAC—The functions of the committee are to review proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.	Immediately
Certain Panels of the Medical Devices Advisory Committee—The medical device panels perform the following functions: (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 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.	
Circulatory System Devices Panel	July 1, 2009
Ear, Nose and Throat Devices Panel	November 1, 2008
Neurological Devices Panel	December 1, 2008
Obstetrics and Gynecology Devices Panel	February 1, 2009

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 contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. 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 committee or 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. Qualifications

A. DGMPAC

Persons nominated for membership as an industry representative on the DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs for this committee are listed in section II of this document.

B. Medical Devices Advisory Committee

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.

V. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee or panel of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee or 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.

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: September 3, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–21016 Filed 9–10–08; 8:45 am]

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