

5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- Ridley, D.B., H.G. Grabowski, and J.L. Moe, "Developing Drugs for Developing Countries," *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 22, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–N–0001]

**Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee**

**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 panels of the Medical Devices Advisory Committee (MDAC or Committee) 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 current and

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 the FDA by October 30, 2017 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by October 30, 2017.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA’s Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Margaret Ames, Division of Workforce Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5264, Silver Spring, MD 20993, 301–796–5960, Fax: 301–847–8505, email: [margaret.ames@fda.hhs.gov](mailto:margaret.ames@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency is requesting nominations for nonvoting industry representatives to

the panels listed in the table in this document.

**I. Medical Devices Advisory Committee**

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

Panels	Function
<i>Circulatory System Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory and vascular systems and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>Clinical Chemistry and Clinical Toxicology Devices Panel.</i>	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 of Food and Drugs.
<i>Gastroenterology and Urology Devices Panel.</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology, and nephrology devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>General Hospital and Personal Use Devices Panel.</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control, and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>Obstetrics and Gynecology Devices Panel.</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in obstetrics and gynecology and makes appropriate recommendations to the Commissioner of Food and Drugs.

Panels	Function
<i>Ophthalmic Devices Panel</i> .....	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs.

## 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 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 panel of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) 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 particular device panels listed in the table. (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.

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 22, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0330]

### Agency Information Collection Request. 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before November 27, 2017.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202)795-7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-0330-60D and project title for reference, to [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), the Reports Clearance Officer Sherrette Funn, call 202-795-7714.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper 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.

**Title:** Appellant Climate Survey, Revision.

**Abstract:** The Office of Medicare Hearings and Appeals (OMHA) requests revision to a previously approved information collection request from the Office of Management and Budget (OMB). The annual OMHA Appellant Climate Survey is a survey of Medicare beneficiaries, providers, suppliers, or their representatives who participated in a hearing before an Administrative Law Judge (ALJ) from OMHA. Appellants dissatisfied with the outcome of their Level 2 Medicare appeal may request a hearing before an OMHA ALJ. The Appellant Climate Survey will be used to measure appellant satisfaction with their OMHA appeals experience, as opposed to their satisfaction with a specific ruling. OMHA was established by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108-173) and became operational on July 1, 2005. The MMA legislation and implementing regulations issued on March 8, 2007 instituted a number of changes in the appeals process. The MMA legislation also directed HHS to consider the feasibility of conducting hearings using telephone or video-conference (VTC) technologies. In carrying out this mandate, OMHA makes use of both teleconferencing and VTC to provide appellants with a vast nationwide network of access points for hearings close to their homes. The first 3-year administration cycle of the OMHA survey began in fiscal year (FY) 2008, a second 3-year cycle began in FY2011, and third 3-year cycle began in FY2014. The survey will continue to be conducted annually over a 3-year period with the next data collection cycle beginning in FY2018. Data collection instruments and recruitment materials will be offered in English and Spanish. Total burden for survey respondents is 100.00 hours each year.

**Affected Public:** Survey respondents will consist of Medicare beneficiaries and non-beneficiaries (*i.e.*, providers, suppliers), who participated in a hearing before an OMHA ALJ. OMHA will draw a representative, non-redundant sample of appellants whose