TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
170.36(c)(v) (CFSAN)	40	1	40	15	600
570.36(c)(v) (CVM)	20	1	20	15	300
Total					900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03330 Filed 2–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–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) 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. 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.

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 by March 21, 2016, (see sections I and II for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by March 21, 2016.

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 may 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 *http://www.fda.gov/AdvisoryCommittees/default.htm*.

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5215, Silver Spring, MD 20993, 301–796–5960, Fax: 301–847–8505, *margaret.ames@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to certain panels identified in the following paragraphs:

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 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 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 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 of Food and Drugs 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.

A. Anesthesiology and Respiratory Therapy Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in anesthesiology and respiratory therapy and makes appropriate recommendations to the Commissioner of Food and Drugs.

B. Ear, Nose and Throat Devices Panel

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

C. Gastroenterology and Urology Devices Panel

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.

D. General and Plastic Surgery Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general and plastic surgery devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

E. 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 of Food and Drugs.

F. Medical Devices Dispute Resolution

Provides advice to the Center Director on complex or contested scientific issues between the 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.

G. 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 of Food and Drugs.

H. 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 of Food and Drugs.

I. Neurological Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the neurological system and makes appropriate recommendations to the Commissioner of Food and Drugs.

J. Orthopaedic and Rehabilitation Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational orthopedic and rehabilitation devices and makes appropriate recommendations to the Commissioner of Food and Drugs.

K. Radiological Devices Panel

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational diagnostics or therapeutic radiological and nuclear medicine devices 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 Committee of interest may be submitted 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 panel. (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: February 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–03283 Filed 2–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier OS–4040–0005 60D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Electronic Government Office, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Electronic Government Office (EGOV), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a 3-year extension for OMB Control Number 4040–0005. The ICR will expire on July 31, 2016. The ICR also requests categorizing the form as a common form, meaning HHS will only request approval for its own use of the form rather than aggregating the burden estimate across all Federal Agencies as was done for previous actions on this OMB control number. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before April 18, 2016.