



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0366]

Agency Information Collection Activities: Proposed Collection; Comment Request; Collection of Nominations for Candidates To Serve on the Food and Drug Administration's Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Agency's process for collecting nominations of candidates to serve on FDA's advisory committees.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-0366 for "Agency Information Collection Activities: Proposed Collection; Comment Request; Collection of Nominations for Candidates to Serve on FDA's Advisory Committees." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Process for Collecting Nominations of Candidates to Serve on FDA's Advisory Committees

OMB Control Number 0910-NEW

FDA chooses to select advisory committee members through a nomination process.¹ A person can self-nominate or be nominated by another individual. In order to identify and select qualified individuals to serve on its advisory committees, FDA has established an online portal, the FDA Advisory Committee Membership Application, to accept nominations of potential advisory committee members.

The FDA Advisory Committee Membership Application accepts applications for Academician/Practitioner, Consumer Representative, and Industry Representative membership types. Nominees who are nominated as scientific members should be technically qualified experts in the field (e.g., clinical medicine, engineering, biological and physical sciences, biostatistics, food sciences) and have experience interpreting complex data. Candidates must be able to analyze detailed scientific data and understand its public health significance. The nomination process has recently been made electronic and is available at <http://accessdata.test.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. To submit an application, prospective nominees should upload the following documents in PDF format²: (1) Curriculum vitae (CV); (2) a written confirmation that the nominee(s) is aware of the nomination (unless self-nominated); and (3) letters of recommendation are also suggested.

¹ Key point and principle I. of Appendix A to Subpart C of 41 CFR 102-3, the Federal Advisory Committee Management Final Rule notes that the Federal Advisory Committee Act does not specify the manner in which advisory committee members and staff must be appointed.

² 21 CFR 14.82(c).

For Consumer Representative applications, a cover letter that lists consumer or community organizations for which the candidate can demonstrate active participation is also recommended.

These documents are collected in order to determine if the nominee has the expertise in the subject matter with which the committee is concerned and has diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it (21 CFR 14.80(b)(1)(i)). In the case of Industry and Consumer Representatives, information is collected to assess the candidate's ability to represent all interested persons within the class which the member is selected to represent (21 CFR 14.86).

Each nominee should be sure to review the Agency Web site for information on:

- Vacancies, Qualifications, and Experience for more details concerning vacancies on each committee and the qualifications and experience common for nominees. Vacancies are updated periodically; therefore, one or more vacancies listed may be in the nomination process or a final appointment may have been made.
- Potential Conflicts of Interest such as financial holdings, employment, and research grants and/or contracts in order to permit evaluation of possible sources of conflict of interest.

Also, FDA asks that prospective nominees inform us of how they heard about the FDA Advisory Committees (e.g., attendance at a professional meeting, an article in a publication, our Web site, while speaking with a friend or colleague).

To further the Agency's goals of promoting transparency regarding the advisory committee process, FDA will also require that nominees to serve on advisory committees submit

a consent form authorizing FDA to publicly post to FDA's Web site the CV submitted as part of their nomination materials, if the nominee is selected to serve on an advisory committee. In the past, FDA generally has posted the CVs of FDA advisory committee members publicly on <http://www.fda.gov/AdvisoryCommittees/> after reviewing the CVs and redacting information that appeared to be confidential. However, in furtherance of FDA's goal of ensuring transparency regarding the qualifications of individuals selected to serve on FDA advisory committees, and in recognition that individual advisory committee members are best situated to evaluate the confidentiality of information contained in their CVs, including any considerations raised by their relationships and agreements with third parties, FDA will now be requiring that all CVs submitted as part of the nomination process for positions on FDA advisory committees be accompanied by a written consent form stating that, if the nominee is accepted as a member of an FDA advisory committee, the individual consents to the publication of the individual's CV to FDA's Web site, without FDA removing or redacting any information. The consent form requires that the nominee affirm that the CV does not include any confidential information, including information pertaining to third parties that the nominee is not permitted to disclose. A nominee will be required to submit a signed consent form as a part of the nomination package in order for the nomination to be considered complete.

All nominations for new advisory committee members will be required to be submitted through FDA's Web site at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, or any successor system, and the submission will be required to be accompanied by the consent form, on or after the date of OMB approval for this information collection.

An estimate of the burden of this collection is provided in table 1. FDA expects that 138.25 burden hours will be expended annually by respondents to the collection of information. FDA estimates that 553 respondents will each submit 1 application for a total of 553 annual responses. We estimate each response will require an average of 0.25 hours (15 minutes) for a total of 138.25 annual hours.

Our estimate of 553 respondents is based on averaging the number of nomination submissions we have received over the past 5 fiscal years. In fiscal year (FY) 2011 we received 638 submissions; FY 2012, 603 submissions; FY 2013, 622 submissions; FY 2014, 545 submissions; and FY 2015, 357 submissions. We believe that each submission will require 15 minutes based on our experience with the submission portal.

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Part 14; Subpart E-- Members of Advisory Committees	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Advisory Committee Membership Applications	553	1	553	0.25 (15 minutes)	138.25

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

Dated: February 1, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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