FOOD AND DRUG ADMINISTRATION
Advisory Committee Membership Nominations

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration's ("FDA") Advisory Committees are established to advise or make recommendations on matters of public health that come before the agency. The Federal Advisory Committee Act (5 U.S.C. App. 2 § 3, P.L. 92-463) ("FACA") defines what constitutes an "advisory committee" under the Act and provides general procedures to follow for the operation of advisory committees. In addition, FACA is designed to assure that the Congress and the public are kept informed with respect to the purpose, membership, and activities of advisory committees. FDA regulations at 21 CFR Part 14 also establish procedures applicable to its advisory committees.

FACA does not specify the manner in which advisory committee members and staff must be appointed. (*See generally* 5 U.S.C. App. 2 . *See also*, 41 CFR §§ 102-3.105, 102-3.130(a)). FDA's regulations, however, specify that the Commissioner "will publish one or more notices in the Federal Register each year requesting nominations for voting members of all existing standing advisory committees." (21 CFR § 14.82(a)). Nominations must specify the committee for which the nominee is recommended, include a complete CV, state that the nominee is aware of the nomination and willing to serve, and state that the nominee appears to have no conflict of interest that would preclude membership. (21 CFR § 14.82(c)). In an effort to promote transparency, consistent with FDA and General Services Administration ("GSA") policy (*See*, GSA regulations encouraging agencies to "practice openness" and suggesting that "agencies may wish to explore the use of the Internet to post advisory committee information …" 41 CFR § 102-3.95(d)), and pursuant to a settlement agreement in the case Public Citizen Foundation, Inc. v. Food & Drug Administration, et al., No. 16-cv-781 (D.D.C.), FDA is also seeking consent from nominees for FDA to publicly post their CVs in the event they are selected to serve on an FDA advisory committee.

Accordingly, FDA is requesting approval for the information collection provisions associated with its Advisory Committee Membership Nomination process.

2. Purpose and Use of the Information Collection

FDA has a total of 50 advisory committees and panels and convenes, on average, 60 advisory committee meetings per year. There are, on average, 9 committee members on each committee or panel. In addition to its standing members, FDA invites additional expert consultants to participate in committee meetings as needed. To ensure that its advisory committees are

staffed with the necessary members and consultants, FDA must establish a repository of candidates that have the necessary qualifications to provide technical and scientific advice for a wide range of meeting topics.

FDA chooses to select advisory committee members through a nomination process. 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 nominations are collected in order to determine if the nominee has the expertise in the subject matter with which the committee is concerned, and if the nominee 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(c)). To further the agency's goals of promoting transparency regarding the advisory committee process, FDA will also require that nominees submit a consent form authorizing FDA to publicly post to FDA's Web site the CV submitted as part of their nomination materials, in the event that the nominee is selected to serve on an advisory committee.

FDA believes that publishing the entire CV of new advisory committee members without redaction will increase public confidence that FDA's review of advisory committee membership nominations and the subsequent selection process has been conducted thoroughly and objectively, without regard to politics or relationships with third parties. Applying this policy across all FDA advisory committees further supports FDA's goal of maintaining science as the primary determinant in agency decision making. FDA does not believe that requiring prospective members to consent to the posting of their CVs, in the event they are selected for membership, will have a negative impact on the number of nominations received. Advisory committee members are compensated by FDA for their service, and the requirement to consent to publication of their CVs imposes only a minimal burden. Such posting will provide an additional level of accountability for officials that make decisions of great significance to FDA, industry, and the public at large.

Finally, under of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" at 21 U.S.C. § 379d-1(e))[1] FDA is required to annually report to Congress on, *inter alia*, its advisory committee vacancies, the number of persons nominated for membership in FDA's advisory committees, the number of nominees who are selected to serve on FDA's advisory committees, and the number of nominees who were asked to serve, but unable to participate due to a financial conflict of interest. The collection of information through the application portal helps FDA to meet this reporting requirement.

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[1] 21 U.S.C. § 379d-1(e). This annual report requirement was added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), signed into law on September 27, 2007, and amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), effective October 1, 2012. Title VII of FDAAA added new conflict of interest provisions applicable to FDA advisory committees, effective October 1, 2007.

3. Use of Improved Information Technology and Burden Reduction

The information collection provides for electronic submissions. To minimize burden on respondents, FDA has established an applicant portal on its website at: https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm through which submissions are made to the agency. To facilitate reporting we have established a standardized format for information data elements and a separate field for uploading necessary documentation. Finally, updated CVs are collected annually from industry representatives currently serving on FDA's advisory committees through e-communications.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose a significant burden on small entities. Respondents to the collection are private individuals who nominate other individuals to serve on FDA advisory committees, or are private individuals submitting self-nominations to serve on FDA advisory committees.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with existing laws and regulations. Under 21 U.S.C.§ 379d-1(b)(1)(C), FDA must solicit referrals of potential new advisory committee members at least every 180 days. Accordingly, under agency regulations, the Commissioner of Food and Drugs will publish "one or more notices in the Federal Register each year requesting nominations for voting members of all existing standing advisory committees." (21 CFR § 14.82(a)). Similarly, and except for committees established by statute, the Commissioner "will issue a Federal Register notice certifying that the establishment or renewal [of an advisory committee] is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend §14.100 to add it to the list of standing advisory committees." (21 CFR § 14.40.)

7. Special Circumstances Relating to the Guidelines in 5 CFR § 1320.5

There are no special circumstances related to the information collection.

8. Comments in Response to the Proposed Rule and Efforts to Consult Outside the Agency

In the Federal Register of February 6, 2017 (82 FR 9383) FDA published a notice requesting public comment on the proposed information collection. One comment was received in support of the information collection, and it recommended no changes to the agency's burden estimate. On our own initiative, however, we have revised the estimate provided in our 60 day notice to reflect an increase of 23.5 burden hours and 94 responses. While we believe our original burden estimate accurately reflects the time burden associated with providing the specific data elements, we have increased the number of respondents to the collection to include Industry Representative members of FDA advisory committees. These burden estimates are discussed in more detail under Question 12a, below.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

While FDA makes no promise of confidentiality, information provided by respondents is covered by two applicable System of Record Notifications (SORNs):

- SORN 09-90-0080 – *The Secretary's Advisory Committee Candidate Files, HHS/OS/ES*: this covers individuals who are being considered for membership on advisory committees within the jurisdiction of the Department of Health and Human Services; and

- SORN 09-90-0059 – *Federal Advisory Committee Membership Files, HHS/OS/ASPER*: this covers individuals who have been or are presently members of, or are being considered for membership on, advisory committees within the jurisdiction of the Department of Health and Human Services. Additionally this system of records contains information about members of the public who have requested that they receive various publications through the inclusion of their names and addresses on various mailing lists.

Notice of the applicability of the SORNs and circumstances under which information submitted to the portal may be released by the agency is provided in the Advisory Committee Application portal. The notification includes a statement that FDA will routinely post the CVs of nominees selected to serve on its advisory committees.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimates

Based on a review of data, we received 638 nominations for membership to FDA advisory committees in Fiscal Year (FY) 2011; we received 603 nominations in FY 2012; we received 622 in FY 2013; we received 545 in FY 2014; and we received 505 nominations in FY 2015. By averaging the number of nominations received annually over the past five years, we estimate there are approximately 583 respondents to the information collection. We estimate it takes respondents 15 minutes to complete an initial application, where accompanying documentation is already available or has been prepared in advance by respondents. Multiplying 15 minutes (0.25) by the number of respondents to the information collection (583) equals 145.75 annual burden hours.

We have also included a burden estimate for members who currently serve on FDA advisory committees who are not Special Government and Regular Government Employees and who must submit an updated CV and an executed/completed consent form annually. Currently there are 64 authorized positions for these Representative members, mostly Industry Representatives. While some positions are vacant, we anticipate the positions will be filled during the year. The request for the updated CV and consent will be made through email communications by the Designated Federal Officer of the committee. The burden to the respondent is anticipated to be the same as the burden for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 16 annual hours.

We therefore estimate the burden of the collection of information as follows:

Table 1 – Estimated Annual Reporting Burden[1]

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 Nominations	583	1	583	0.25 (15 minutes)	145.75
Representative Member Submission of Updated Information	64	1	64	0.25 (15 minutes)	16.0
TOTAL			647		161.75

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

12b. Annualized Cost Burden Estimates

We estimate no capital costs to respondents for the collection of information.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA currently devotes approximately 250 hours annually to the review and processing of nominations received through its Advisory Committee Application portal, including advising nominees of their selection. Using an hourly wage rate for the Washington DC/Metropolitan area at the GS-13/1 level ($40), we calculate the cost to the Federal government to be approximately $10,000 annually.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

The nomination packages collected pursuant to this ICR will be used by FDA to select appropriately qualified individuals to serve on its advisory committees. In an effort to promote transparency, consistent with FDA and GSA policy (*see*, GSA regulations encouraging agencies to "practice openness" and suggesting that "agencies may wish to explore the use of the Internet to post advisory committee information …" 41 CFR § 102-3.95(d)), and pursuant to a settlement agreement in the case Public Citizen Foundation, Inc. v. Food & Drug Administration, et al., No. 16-cv-781 (D.D.C.), FDA plans to post on FDA's website, the CVs of nominees that are selected to serve on FDA's advisory committees at the time of their selection. FDA does not plan to make public other application materials of advisory committee members, or the CVs of nominees who are not selected to serve on FDA advisory committees.

Consistent with notice published in the Federal Register of February 6, 2017 (82 FR 9382), FDA has already begun soliciting updated CVs and consent forms from currently serving advisory committee members and publicly posting those CVs on FDA's website. While such information collection from Regular and Special Government Employees is exempt from OMB review under the PRA, FDA's currently serving advisory committee members have been cooperating with implementation of this new policy. Pursuant to this policy therefore, CVs of currently-serving advisory committee members will be posted on a rolling basis as members update their information with the agency.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB Expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.