TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

User fee waivers, reductions, & refunds for drug & biological products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					2,630

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

Dated: May 18, 2017.

Anna K. Abram,

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

[FR Doc. 2017–10534 Filed 5–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Advisory Committee Nomination Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 22, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number, 0910–NEW, and title, ''FDA Advisory Committee Membership Nominations.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, we have submitted the following proposed collection of information to OMB for review and clearance.

FDA Advisory Committee Membership Nominations—OMB Control Number 0910–NEW

FDA chooses to select advisory committee members through a nomination process. (Appendix A to Subpart C of 41 CFR 102–3, the Federal Advisory Committee Management Final Rule notes that the Federal Advisory Committee Act (FACA, 5 U.S.C. App. 2) does not specify the manner in which advisory committee members and staff must be appointed.) 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 nominations 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 a nomination, nominators or prospective nominees should upload the following documents in PDF format (see 21 CFR 14.82(c)): (1) Curriculum vitae (CV); (2) a written confirmation that the nominee(s) is (are) aware of the nomination (unless self-nominated); and (3) letters of recommendation are also suggested. For Consumer Representative nominations, 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 has generally 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 nominee consents to the publication of the nominee'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 *http://accessdata.test.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.

In the **Federal Register** of February 6, 2017 (82 FR 9383), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the information collection and 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, but we have increased the number of respondents to the collection to include Industry Representative members of FDA advisory committees.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 14; subpart E—members of advisory committees	Number of respondents	Number 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.

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 5 years, we estimate there are approximately 583 respondents to the information collection. We estimate it takes respondents 15 minutes to complete an initial nomination, 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. We anticipate that the burden to the respondent will be the same as that for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 16 annual hours.

Dated: May 18, 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–2010–N–0588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice