Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08009 Filed 4–15–20; 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) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by May 18, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0833. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

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

FDA Advisory Committee Membership Nominations

OMB Control Number 0910–0833

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 regulations note 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 website 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 website, 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 post, without removing or redacting any information, to FDA's public website (*http://www.fda.gov/AdvisoryCommittees*) the CV submitted as part of their nomination materials if the nominee is selected to serve on an advisory committee. 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 for the nomination to be considered complete.

All nominations for new advisory committee members will be required to be submitted through FDA's website 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 January 7, 2020 (85 FR 718), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received but were not responsive to the information collection topics solicited under the PRA.

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	391	1	391	0.25 (15 minutes)	98
Representative Member Submission of Updated Information	54	1	54	0.25 (15 minutes)	14
Total			445		112

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

Based on a review of data, we received 354 nominations for membership to FDA advisory committees in fiscal year (FY) 2015; we received 510 nominations in FY 2016; we received 500 nominations in FY 2017; we received 258 nominations in FY 2018; and we received 333 nominations in FY 2019. By averaging the number of nominations received annually over the past 5 years, we estimate there are approximately 391 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 (391) equals 97.75 (98 rounded) 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 54 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 form 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 13.5 (14 rounded) annual hours.

Dated: April 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08008 Filed 4–15–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0622]

Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 solicits comments on the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

DATES: Submit either electronic or written comments on the collection of information by June 15, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 15, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 15, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and