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; Food and Drug Administration Advisory Committee Regulations

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.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 Regulations

OMB Control No. 0910-0833--Revision

This information collection helps support implementation of FDA regulations found in part 14 (21 CFR part 14). These regulations govern procedures applicable to presenting information and views before an FDA advisory committee in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 and 3, Pub. L. 92-463). FACA is designed to assure that Congress and the public are kept informed with respect to the purpose, membership, and activities of advisory committees. It does not specify the manner in which advisory committee members and staff must be appointed.

Public advisory committee regulations in part 14 set forth requirements governing the administrative procedures to follow for the operation of advisory committees. Agency regulations in part 14, subpart A (§§ 14.1 through 14.15) identify scope of coverage, applicable definitions, and establish general provisions. The regulations in part 14, subpart B (§§ 14.20 through 14.39) set forth content and format requirements along with required schedules for submission of information. The regulations in part 14 subparts C, D, and E (§§ 14.40 through 14.95) set forth requirements governing advisory committee establishment, recordkeeping, and maintenance, respectively.

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 curriculum vitae (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. Although we are developing collection instruments, as communicated on our website, respondents may submit information to: Advisory Committee Oversight and Management Staff, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 800-741-8138 or 301-443-0572.

In the *Federal Register* of February 13, 2023 (88 FR 9294), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received but were not responsive to the information collection topics solicited under the PRA. On our own initiative, we are clarifying the scope of coverage for the information collections.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Part 14	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Subpart E--Members of Advisory Committees					
Advisory Committee Membership Nominations	308	1	308	0.25 (15 minutes)	77
Member Submission of Updated Information	452	1	452	0.25 (15 minutes)	113
Total					190

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

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: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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