

- The flexibility built into the review timeline, including the ability for review divisions to request review clock extensions to ensure reviews of the highest scientific quality.

- The relationship between CNPV Pilot Program target timelines and PDUFA goal dates.

- The use of optional tools (e.g., review templates, AI tools) to facilitate review or tracking of applications.

- The CNPV Review Council, as outlined in the *FDA Staff Manual Guide on Commissioner's National Priority Voucher Review Council*,¹ including any comments on:

- The role of the CNPV Review Council in providing recommendations to the relevant Center Director regarding application approvability with respect to the part(s) of the application presented to the Council for consideration.

- The “tumor board style” meeting format, including application presentation, discussion, primary review team recommendation, Council vote, and Center Director recommendation.

- The Sponsor Responsibilities and Expectations, including any comments on the following processes/procedures:

- FDA’s request for written acknowledgment and confirmation of sponsor or applicant’s agreement to participate within two weeks of voucher issuance.

- FDA’s clarity of communication regarding the fact that a voucher does not guarantee approval or a 1–2 month timeframe.

- FDA’s expectation that the intent to redeem voucher should ideally be acknowledged within 2 weeks of official issuance date.

- FDA’s expectation that sponsors submit complete application within 2 years of official voucher issuance date.

- FDA’s request for sponsors to share public announcements related to the CNPV Pilot Program with FDA prior to release.

- The Program Evaluation and Future Directions, including any comments on

- Metrics or outcomes FDA should consider in evaluating the program’s success.

- What the Agency should consider for continuing, modifying, or expanding the program based on pilot results.

- Other topics, issues, or concerns related to the CNPV Pilot Program that stakeholders wish to address, such as suggestions for improving the program design, implementation, or communication, and potential unintended consequences of the program and how they might be mitigated.

IV. Participating in Public Hearing

Registration: To register to attend or participate in the free public hearing, please visit the following website: <https://www.fda.gov/news-events/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-06122026>.

Registration will open on April 1, 2026. Live closed captioning will be provided during the public hearing. Additional information on requests for special accommodations due to a disability will be provided during registration.

Written Notice of Participation: During online registration you may indicate if you wish to present information and views at the hearing (oral statements without slides). FDA will do its best to accommodate requests to make public presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants ahead of the hearing. All written requests for participation must be received by May 1, 2026, 11:59 p.m. Eastern Time (email to: CommissionerVoucher@fda.hhs.gov). No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at <https://www.regulations.gov>. Once available, the transcript may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–05573 Filed 3–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2364]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration 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, 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 associated with certain FDA advisory committee activities.

DATES: Either electronic or written comments on the collection of information must be submitted by May 22, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 22, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2026-N-2364 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Advisory Committees.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **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 Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5661, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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.

FDA Advisory Committees—21 CFR Part 14

OMB Control Number 0910-0833—Extension

This information collection supports certain Food and Drug Administration (FDA, the Agency, us or we) Advisory Committee administrative activities. 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, Pub. 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. 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.

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 curriculum vitae (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(b)),

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN^{1 2}

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	407	1	407	0.25 (15 mins.)	102
Member Submission of Updated Information	359	1	359	0.25 (15 mins.)	90
Total					192

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

² Sums may not total due to rounding.

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–05623 Filed 3–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2365]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees

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 solicits comments on the information collection provisions of FDA’s animal drug and animal generic drug user fee programs.

DATES: Either electronic or written comments on the collection of

information must be submitted by May 22, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 22, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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–2026–N–2365 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **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