§ 571.6 Amendment of Petition: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, 5 respondents will each submit 1 such amendment, for a total of 6,500 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, 8 respondents will each submit 1 such file, for a total of 12,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, 10 respondents will each submit 1 such file, for a total of 50,000 hours.

Consultation Category: We estimate developers of animal food ingredients will spend 3,000 hours consulting with FDA on an ingredient. We estimate that, annually, 12 respondents will consult with FDA, for a total of 36,000 hours.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements for a particular color additive or food additive involve information required as part of the safety review process, the burden hours for labeling are included in the estimate for 21 CFR 501.22(k) and 571.1.

We base our estimate of the total annual responses on submissions received over the last 3 years. We base our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

Based on review of the information collection, there was a decrease of food additive petition (FAP) responses and a corresponding decrease in burden hours for FAPs. We attribute this adjustment to an increase in the number of GRAS notices (21 CFR part 570, subpart E) received, which tend to substitute for FAP submissions due to a similar quantity and quality of data and information requirement. These numbers can fluctuate year to year. We also note that investigational food additive file responses have increased due to more respondents providing information during the pre-market process prior to providing a more formal regulatory response (*e.g.,* FAP or GRAS notice). We did not adjust the number of responses received for the declaration of color additives on animal food labels from the previous collection.

Our estimated burden for the information collection reflects an overall increase of 40,600 total hours and 24 responses. We attribute this to accounting for the consultation process for firms developing animal food ingredients.

Dated: December 12, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30227 Filed 12–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1055]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, us, 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.

DATES: Submit written comments (including recommendations) on the collection of information by January 21, 2025.

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 0910–0847. 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, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-making processes and communications that affect various stakeholders. FDA uses the following methodology to achieve these goals: (1) creation and validation of survey instruments; (2) use of techniques to evaluate sampling and recruitment methods; (3) evaluation of the validity and reliability of survey instruments; (4) individual in-depth interviews, (5) general public focus group interviews, (6) intercept interviews, (7) self-administered surveys, (8) gatekeeper surveys, and (9) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful, valid, and reliable information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- Successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials. These subjects include social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Further, in addition to overseeing the safety of drug products when used according to approved drug labeling or as directed by a healthcare provider, CDER conducts studies on topics related to the safe and effective use of drug products, and emerging safety issues in areas such as: (1) nonmedical use of approved drug products; (2) use of unapproved and falsified (*i.e.,* counterfeit, fake) drug products; (3) use of botanical substances (*e.g.,* cannabis derived products); (4) controlled substance prescribing decisions; (5) bystander response to drug overdoses; and (6) potentially false or misleading information about drug products. Reliable data on these and related topics are a critical first step to understanding whether further studies or action is needed to protect public health.

Because often data on these topics are not collected as part of routine healthcare delivery or via established Federal surveys, FDA requires the development and validation of novel instruments (*i.e.,* interview and focus group guides, questionnaires) and approaches to gathering data on emerging safety issues the methods used to create and validate these instruments may include interviews, focus groups, small group discussions, pilot and test/re-test survey launches, and external validation against benchmark surveys. In conducting research in these areas, FDA will need to employ the following validation methodology: (1) research to assess knowledge, perceptions, and experiences related to topics in the above-mentioned areas with specific target populations; (2) techniques to evaluate sampling and recruitment methods; and (3) evaluations of the validity and reliability of survey questionnaires in target populations.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment on the proposed collection of information in the **Federal Register** of April 23, 2024 (89 FR 30381). Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

Annually, FDA projects about 25 social and behavioral studies using the variety of test methods listed in this document. FDA is revising this burden to account for the number of studies we have received in the last 3 years and to better reflect the scope of the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews and Surveys	126,770	1	126,770	0.25 (15 minutes)	31,693

[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, our burden estimate for this information collection reflects an overall increase of 17,300 responses with a corresponding increase of 4,325 hours. We attribute this adjustment to the need to validate information in specific areas.

Dated: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–30224 Filed 12–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meetings of the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Council on Graduate Medical Education (COGME or Council) will hold public meetings for the 2025 calendar year (CY). Information about COGME, agendas, and materials for these meetings can be found on the COGME website at: *https://www.hrsa.gov/advisory-committees/graduate-medical-edu.*

DATES: COGME meetings will be held on:

- April 10, 2025, 8 a.m.–5 p.m. eastern time (ET) and April 11, 2025, 8 a.m.–2 p.m. ET.
- September 11, 2025, 8 a.m.–5 p.m. ET and September 12, 2025, 8 a.m.–4 p.m. ET.

ADDRESSES: Meetings will be held in-person, by teleconference, and/or on a video conference platform. In-person meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For updates on how the meetings will be held, instructions for joining meetings, and any other updates, visit the COGME website 30 business days before the date of the meeting at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Officer, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N39, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME provides advice and recommendations to the Secretary of HHS and Congress on policy, program development, and other matters of significance regarding the issues listed in section 762(a)(1) of the Public Health Service Act. Issues addressed by the COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses, issues related to foreign medical school graduates, the nature and financing of undergraduate and graduate medical education, appropriation levels for certain programs under title VII of the Public Health Service Act, and deficiencies in databases concerning the supply and distribution of the physician workforce and postgraduate programs for training