Federal Supplementary Medical Insurance Trust Fund for certain Part D drugs when prices increase faster than the rate of inflation for each 12-month applicable period. Collectively, this program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program, or the Inflation Rebate Program.

CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website at *https://www.cms.gov/inflation-reduction-act-and-medicare/.*

To obtain copies of initial guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: *https://www.cms.gov/inflation-reduction-act-and-medicare.* If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at *https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates.*

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 8, 2023.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–02974 Filed 2–9–23; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

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, the 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 associated with certain FDA advisory committee activities.

DATES: Either electronic or written comments on the collection of information must be submitted by April 14, 2023.

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 April 14, 2023. 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–2017–N–0366 for ''FDA 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: 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: 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; Information Collection Activities

OMB Control No. 0910–0833—Revision

This information collection supports certain FDA 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 (FACA) (5 U.S.C. App. 2 3, Pub. L. 92–463) defines what constitutes an ''advisory committee'' and provides general procedures to follow for the operation of advisory committees. In addition, FACA is designed to assure that Congress and the public are kept informed with respect to the purpose, membership, and activities of advisory committees. FDA regulations at 21 CFR part 14 also establish procedures applicable to its advisory committees.

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, and 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'' (§ 14.82(a) (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 (§ 14.82(c)). 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(d)), 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 are revising the information collection to include reporting activities associated with Guest Speakers. Guest Speakers are individuals who are occasionally asked to present technical and scientific data pertaining to matters being considered by an FDA advisory committee. Guest Speakers are not Government employees or are special Government employees participating in a non-official, non-governmental capacity. Guest Speakers are therefore not subject to the conflict-of-interest statutes and regulations, including appearances of a conflict of interest (5 CFR 2635.502).

Seeking transparency and openness, the Agency has determined it would be appropriate policy to request that a Guest Speaker voluntarily disclose financial interests and professional relationships to determine their eligibility to give a presentation at an advisory committee meeting.[1] [2] Disclosures reported to the Agency by Guest Speakers that are related to a meeting topic will be disclosed to the public as part of the conflict-of-interest statement at the beginning of a meeting. This will allow the committee to objectively evaluate the Guest Speaker's presentation.

Because not all Guest Speakers are current Federal Government or Special Government employees bound by applicable statutory requirements and implementing regulations that govern financial disclosure and other conflicts of interest, we are instituting procedures in this regard. However, we intend to utilize FORM OGE 450, ''Office of Government Ethics Form'' and/or Form FDA 3410, to determine eligibility for Federal Government employees or special Government employees participating in an official governmental capacity to give a presentation to an advisory committee. To assist respondents with the reporting elements associated with these forms, we have prepared the procedural guidance document for the public, FDA advisory committee members, and FDA staff entitled ''Public Availability of Advisory Committee Members' Financial Interest Information and Waivers'' (March 2014). The guidance is available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/public-availability-advisory-committee-members-financial-interest-information-and-waivers* and was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provides for comment at any time. For submission of Guest Speaker forms we have prepared a procedural staff manual guide (SMG), ''Guidelines for Clearance of Conflicts of Interest of Speakers Participating in Particular Matters Before an Advisory Committee.'' SMGs are available for download at *https://www.fda.gov/about-fda/reports-manuals-forms/staff-manual-guides.*

Accordingly, we are requesting approval for information collection associated with FDA advisory committee membership nominations, as well as collection associated with determining the eligibility of Guest Speakers, as discussed in this supporting statement.

[1] A professional relationship is a relationship (not including a transactional business relationship) with a firm, association, society, supervisor, partner, colleague, mentor, or other persons in an individual's professional network. These relationships include, but are not limited to, employer—employee; professional—client; society—professional; or professional—professional.

[2] Although screening is voluntary for Guest Speakers, as a policy matter, FDA generally conditions a Guest Speaker's participation in the meeting upon completion of the screening form because an assessment of potentially disqualifying interests can only be completed if the necessary information requested on the form is disclosed to the Agency.

Based on a review of data, we received 258 nominations for membership to FDA advisory committees in fiscal year (FY) 2018; 333 nominations in FY 2019; 254 nominations in FY 2020; 289 nominations in FY 2021; and 408 nominations in FY 2022. By averaging the number of nominations received annually over the past 5 years, we estimate there are approximately 308 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 (308) equals 77 annual burden hours.

We have also included a burden estimate for members who currently serve on FDA advisory committees who must submit an updated CV and a completed consent form annually. Currently, there are 532 authorized positions for advisory committee members. While many positions are filled, there are generally about 15 percent of member positions vacant, which leaves an average of 452 respondents. The request for the updated CV and consent form will be made through email communications by the Designated Federal Officer of the committee. The burden to the respondent is anticipated to be the same as the burden for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 113 annual hours.

To account for burden attendant to reporting information so that FDA may determine respondents' eligibility to serve as Guest Speakers, we include only those individuals who are not Federal Government employees or who are special Government employees acting in a non-official, non-governmental capacity. Based on historical information, approximately 40 Guest Speakers present at advisory committee meetings annually. The request for the form will be made through email communications by the Designated Federal Officer of the committee. We estimate each response will require 15 minutes (0.25) for a total of 10 annual hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 14; subpart E—members of advisory committees activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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
Guest Speakers—Eligibility Form/Attestation	40	1	40	0.25 (15 minutes)	10
Total			800		200

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

As a result of these changes and adjustments, the information collection reflects a decrease in membership nominations, an increase in submissions of updated information, and submission of Guest Speaker forms for an overall increase of 355 responses and 88 hours annually.

Dated: February 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02961 Filed 2–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0112]

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development.'' This guidance is intended to provide a framework for considering whether and what type of long-term neurologic, sensory, and/or developmental evaluations could be useful in supporting a determination of safety of a regulated product for use in neonates, and which domains of assessment may be most pertinent. Although short-term safety evaluations may be acceptable for adults or other populations, such short-term evaluations may not identify important adverse events in the neonatal population, as latent effects may follow early-life exposures and drug treatment during the neonatal period coincides with a time of critical growth and physiologic development. Consideration of these potential long-term neurologic, sensory, and development effects in the neonatal population early in a drug development program will help ensure a safer product.

DATES: Submit either electronic or written comments on the draft guidance by April 14, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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'').