Letters of Interest

The letter of interest is not considered a formal proposal and is not required; however, it is highly recommended as it will assist CDC in planning for the review process. The formal proposal will still need to be submitted according to the instructions in this notice.

Formal Proposals

Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies which have a product that is suitable for regulatory approval and commercialization. This collaboration will have an expected duration of 1 to 4 years.

Dated: June 7, 2023.

Tiffany Brown,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2023–12435 Filed 6–9–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–4040 and CMS–R–297]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by July 12, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Enrollment in Supplementary Medical Insurance (SMI); *Use:* CMS regulations 42 CFR 407.11 lists the CMS–4040 as the application to be used by individuals who are not eligible for monthly Social Security/Railroad Retirement Board benefits or free Part A. The CMS–4040 solicits the information that is used to determine entitlement for individuals who meet the requirements in section 1836 as well as the entitlement of the applicant or their spouses to an annuity paid by OPM for premium deduction purposes. The application follows the application questions and requirements used by SSA. This is done not only for consistency purposes but to comply with other Title II and Title XVIII requirements because eligibility to Title II benefits and free Part A under Title XVIII must be ruled out in order to qualify for enrollment in Part B only. *Form Number:* CMS–4040 (OMB control number: 0938–0245); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 42,011; *Total Annual Responses:* 42,011; *Total Annual Hours:* 10,503. (For policy questions regarding this collection contact Carla Patterson at 410–786–8911.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Employment Information; *Use:* The form CMS–L564, also referred to as CMS–R–297, is used, in conjunction with form CMS–40–B, Application for Supplementary Medical Insurance, during an individual's special enrollment period (SEP). Completed by an employer, the CMS–L564 provides proof of an applicant's employer group health coverage. The Social Security Administration (SSA) uses it to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. The form is available online via *Medicare.gov* and *CMS.gov* for individuals who are requesting the SEP to obtain and submit to their employer for completion. The employer must complete and sign the form, and submit it to the individual to accompany their enrollment or late enrollment penalty reduction request. The information on the completed form is reviewed manually by SSA. *Form Number:* CMS–R–297 (OMB control number: 0938–0787); *Frequency:* Once; *Affected Public:* Individuals or households, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 676,526; *Total Annual Responses:* 676,526; *Total Annual Hours:* 56,355. (For policy questions regarding this collection contact Carla Patterson at 410–786–8911.)

Dated: June 6, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–12396 Filed 6–9–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0134]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 July 12, 2023.

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 0910–0191. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 Administrative Practices and Procedures

OMB Control No. 0910–0191—Revision

This information collection helps support implementation of FDA regulations found in part 10 (21 CFR part 10), parts 12 through 16 (21 CFR parts 12 through 16), and part 19 (21 CFR part 19). These regulations are established in accordance with the Administrative Procedures Act (5 U.S.C. subchapter II) and implement administrative practice and procedures to give instructions to those conducting business with FDA. Regulations in part 10 describe general administrative practices and include content and format instruction on submitting information to the Agency, petitions for Agency action, and other topics such as the public calendar. Regulations in parts 12 through 16 cover formal evidentiary, public, and regulatory hearings. The information collection also includes burden associated with waiver requests under § 10.19 (21 CFR 10.19). Unless a waiver, suspension, or modification submitted under § 10.19 is granted by the Commissioner of Food and Drugs, the regulations in part 10 apply to all petitions, hearings, and other administrative proceedings and activities conducted by FDA. Because information associated with regulations in parts 12 through 16 is obtained during the conduct of an official administrative action as described under 5 CFR 1320.4, we account only for burden we attribute to initiating the respective actions.

The information collection also includes burden associated with general meeting requests and correspondence submitted to FDA under § 10.65 (21 CFR 10.65), as well as general submissions associated with § 10.115 (21 CFR 10.115) which provides for public participation in the development of Agency guidance documents through requests to our Dockets Management Staff. Most burden attributable to recommendations found in FDA guidance documents is accounted for within information collection request approvals respective to the topic-specific guidance document; however here we are accounting for burden associated with general public submissions as described in § 10.115(f)(3).

The information collection also includes burden that may be associated with the procedural guidance document, ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act'' (September 2019), available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act.* The guidance document provides information regarding our current thinking on interpreting section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)) and includes procedural instruction on submitting certain citizen petitions and petitions for stay of FDA action. The guidance document also describes how FDA interprets the provisions of section 505(q) requiring that (1) a petition include a certification and (2) supplemental information or comments on a petition include a verification. It also addresses the relationship between the review of petitions and pending abbreviated new drug applications (ANDAs), 505(b)(2) applications, and 351(k) applications for which a decision on approvability has not yet been made.

In the **Federal Register** of February 7, 2023 (88 FR 7981), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. On our own initiative, however we are revising the information collection to include requests for FDA speakers. As communicated on our website at *https://www.fda.gov/training-and-continuing-education/contacts-requesting-fda-speaker,* FDA receives thousands of requests each year from trade associations and industry-based groups for speakers to participate in external meetings, conferences, and workshops. To facilitate the processing of these requests and direct them appropriately to determine participation, we have developed web-based templates and questionnaires, and have established dedicated points of contact throughout the Agency. We have therefore revised the estimated burden for the information collection as follows: