DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10215, CMS–10249, and CMS–10341]

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 August 9, 2021.

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, you may make your request using one of following:


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, and to allow a second opportunity for public comment. 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, and to allow a second opportunity for public comment.

1. Type of Information Collection Request: Extension of currently approved collection; Title of Information Collection: Identifying Medicaid Payment for Physician Administered Drugs; Use: States are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for “J” code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. Form Number: CMS–10215 (OMB control number: 0938–1026); Frequency: Weekly; Affected Public: Business or other for-profits and Not-
2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Administrative Requirements for Section 6071 of the Deficit Reduction Act; Use: State Operational Protocols should provide enough information such that: the CMS Project Officer and other federal officials may use it to understand the operation of the demonstration, prepare for potential site visits without needing additional information, or both; the State Project Director can use it as the manual for program implementation; and external stakeholders may use it to understand the operation of the demonstration. The financial information collection is used in our financial statements and shared with the auditors who validate CMS’ financial position. The Money Follows the Person Relaunching Demonstration (MFP) Finders File, MFP Program Participation Data file, and MFP Services File are used by the national evaluation contractor to assess program outcomes while we use the information to monitor program implementation. The MFP Quality of Life data is used by the national evaluation contractor to assess program outcomes. The evaluation is used to determine how participants’ quality of life changes after transitioning to the community. The semi-annual progress report is used by the national evaluation contractor and CMS to monitor program implementation at the grantee level. The revisions aim to reduce the reporting burden by presenting a substantially revised and shortened version of the semi-annual progress report. The budget workbook has also been revised to combine two earlier reporting forms. Form Number: CMS–10341 (OMB control number: 0938–1162); Frequency: Yearly and quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 37; Total Annual Responses: 372; Total Annual Hours: 27,914. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.) Dated: July 6, 2021. William N. Parham, III, Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

Food and Drug Administration [Docket No. FDA–2014–N–2347]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificates

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 August 9, 2021.

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 0910–0793. 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, PRASStaff@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.

Food and Cosmetic Export Certificates

OMB Control Number 0910–0793—Extension

Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a “certificate.” In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA. FDA’s Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for human food and cosmetic products. Interested persons may request a certificate electronically via the CFSAN Export Certification Application and Tracking System (CFSAN eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting CFSAN for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. For food products, respondents are able to identify facilities using their Food Facility Registration, an FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter