

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifiers CMS–10141]

**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 March 17, 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](http://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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* Plan sponsor and State information is used by CMS to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS–10141 (OMB control number: 0938–0964); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 4,631,393; *Total Annual Responses:* 95,802,400; *Total Annual Hours:* 25,506,943. (For policy questions regarding this collection contact Shelly Winston at 410–786–3694.)

Dated: February 9, 2023.

**William N. Parham, III,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA–2023–D–0169]

**Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability****AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled "Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act." This guidance describes FDA's regulatory and enforcement priorities regarding compounding certain ibuprofen oral suspension products by outsourcing facilities to provide to hospitals and health systems for administration within the hospital or health-system and State-licensed pharmacies (including those within hospitals and health systems), and applicable Federal facilities, to dispense to patients for use at home after receiving a valid, patient-specific prescription. This final guidance revises and replaces the guidance of the same name issued on January 25, 2023. Revisions were made to describe the Agency's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products by outsourcing facilities to provide to State-licensed pharmacies (including those within hospitals and health systems), and applicable Federal facilities, to dispense to patients for use at home after receiving a valid, patient-specific prescription.

**DATES:** The announcement of the guidance is published in the **Federal Register** on February 15, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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