number: 0938–1148); *Frequency:* Once, quarterly, and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 616; *Total Annual Hours:* 1,344. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

Dated: May 14, 2021.

William N. Parham, III,

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

[FR Doc. 2021–10574 Filed 5–19–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10536, CSM–10225 and CMS–10764]

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 June 21, 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:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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:* Medicaid Eligibility and Enrollment (EE) Implementation Advanced Planning Document (IAPD) Template; *Use:* To assess the appropriateness of states' requests for enhanced federal financial participation for expenditures related to Medicaid eligibility determination systems, we will review the submitted information and documentation to make an approval determination for the advanced planning document. *Form Number:* CMS–10536 (OMB control number: 0938–1268); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 2,688. (For policy questions regarding this collection contact Edward Dolly at 410–786–8554.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; *Use:* This information collection relates to the required third party disclosures by certain Medicare-participating hospitals and Critical Access Hospitals (CAHs) and physicians to their patients. There are 5 types of disclosures required. The intent of the disclosure notice is to assist the patient in making an informed decision regarding their care. The first disclosure requires physician owned hospitals and CAHs to disclose to its patients whether the hospitals/CAHs are physician-owned and, if so, the names of the physician-owners. The second disclosure requires the physician owner or investor in the hospital, as part of his or her continued medical staff membership or admitting privileges, to disclose to the patient being referred to the hospital any ownership or investment interest held by the physician or an immediate family member of the physician. The third disclosure requires physician owned hospitals to disclose on all public websites for and in any public advertising for the hospital that the hospital is owned or invested in by physicians. The fourth and fifth disclosures apply to all hospitals and CAHs that do not have a Doctor of Medicine (MD) or a Doctor of Osteopathic Medicine (DO) on the premises at all times to disclose this to patients upon admission or registration for both inpatient and specified outpatient services. These hospitals and CAHs must provide a written disclosure to the patients admitted to the hospital and must also post a conspicuous notice in the Emergency Departments (ED) which states that the hospital does not have a physician present 24 hours per day, 7 days per week. *Form Number:* CMS–10225 (OMB control number: 0938–1034); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 210; *Total Annual Responses:* 1,193,890; *Total Annual Hours:* 78,935. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705).

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of Risk Adjustment Data Validation

(RADV) Appeals and Health Insurance Exchange Outreach Training Sessions; *Use:* CMS recognizes that the success of accurately identifying risk-adjustment payments and payment errors is dependent upon the data submitted by Medicare Advantage Organizations (MAOs), and is strongly committed to providing appropriate education and technical outreach to MAOs and third-party administrators (TPAs). In addition, CMS is strongly committed to providing appropriate education and technical outreach to States, issuers, self-insured group health plans and TPAs participating in the Marketplace and/or market stabilization programs mandated by the Affordable Care Act (ACA).

CMS will strengthen outreach and engagement with MAOs and stakeholders in the Marketplace through satisfaction surveys following contract-level (CON) RADV audit and Health Insurance Exchange training events. The survey results will help to determine stakeholders' level of satisfaction with trainings, identify any issues with training and technical assistance delivery, clarify stakeholders' needs and preferences, and define best practices for training and technical assistance. *Form Number:* CMS–10764 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 4,270; *Total Annual Responses:* 4,270; *Total Annual Hours:* 1,068. (For questions regarding this collection contact Melissa Barkai at 410–786–4305.)

Dated: May 17, 2021.

William N. Parham, III,

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

[FR Doc. 2021–10680 Filed 5–19–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0226]

Determination That AVACLYR (Acyclovir Ophthalmic Ointment), 3 Percent, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acyclovir ophthalmic ointment, 3 percent, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455, *Nisha.Shah@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AVACLYR (acyclovir ophthalmic ointment), 3 percent, is the subject of NDA 202408, held by Fera Pharmaceuticals, LLC, and initially approved on March 29, 2019. AVACLYR is indicated for the treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV–1 and HSV–2) virus.

In a letter dated August 21, 2019, Fera Pharmaceuticals, LLC notified FDA that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Cumulus Pharmaceutical LLC submitted a citizen petition dated February 23, 2021, (Docket No. FDA–2021–P–0226), under 21 CFR 10.30, requesting that the Agency determine whether AVACLYR (acyclovir ophthalmic ointment), 3 percent, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AVACLYR (acyclovir ophthalmic ointment), 3 percent, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AVACLYR (acyclovir ophthalmic ointment), 3 percent, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AVACLYR (acyclovir ophthalmic ointment), 3 percent, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Any ANDAs referencing AVACLYR (acyclovir ophthalmic ointment), 3 percent, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.