in PowerPoint presentation format, not PDF. We will not play videos or animations during the public meeting sessions and request the speakers to exclude these materials from their PowerPoint presentation and instead submit any relevant video or animation materials along with the written comments. We request the speakers to ensure that the presentation does not include any inappropriate content before submission.

Every primary speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS application that the primary speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

2. 5-Minute Speakers

Any individual related to the public meeting agenda item, including but not limited to, an employee, stakeholder, competitor, insurer, public consumer, etc., may register and speak as a 5-minute speaker. The deadline for registering to be a 5-minute speaker is 5 p.m., EST, Tuesday, November 14, 2023.

Every 5-minute speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS code application or agenda item that the 5-minute speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant. We will not accept any other written materials, outside of the written comments, from a 5-minute speaker.

3. All Other Attendees

All individuals who plan to attend the virtual public meetings to listen and do not plan to speak, may access the virtual public meeting using the Zoom link posted on the HCPCS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo* after the speaker registration closes on Tuesday, November 14, 2023.

Individuals who require special assistance must register and request special assistance services by 5 p.m. EST, Tuesday, November 14, 2023.

IV. Written Comments

The primary and 5-minute speaker(s) must email a brief, written summary (one paragraph) of their comments and conclusions. Written comments from anyone, including the primary and 5-minute speaker(s), will only be accepted when emailed to: *HCPCS@cms.hhs.gov* before 5 p.m., EST on the date of the virtual public meeting at which the HCPCS code application that is the subject of the comments is discussed.

V. Additional Information

The HCPCS section of the CMS website also *includes* details regarding the public meeting process for new revisions to the HCPCS code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. The HCPCS section of the CMS website also contains a document titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,'' which is a description of the HCPCS coding process, including a detailed explanation of the procedures CMS uses to make HCPCS coding determinations.

When CMS refers to HCPCS code or HCPCS coding application above, CMS may also be referring to circumstances when a HCPCS code has already been issued, but a Medicare benefit category and/or payment has not been determined. CMS is working diligently to address Medicare benefit category and payment determinations for new items and services that may be DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. Please check the CMS website listed above for the final agenda.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–22953 Filed 10–17–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Proposed Collection; Public Comment Request; ACL Generic for Administration on Aging Formula Grant Programs OMB Control Number 0985–New

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a 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 new information collection solicits comments on the information collection requirements relating to the ACL Generic for Administration on Aging Formula Grant Programs.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 18, 2023.

ADDRESSES: Submit electronic comments on the collection of information to: Adam Mosey, *Adam.Mosey@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Adam Mosey.

FOR FURTHER INFORMATION CONTACT: Adam Mosey (202) 795–7631 or *Adam.Mosey@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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. The PRA 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, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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 using automated collection techniques when appropriate, and other forms of information technology;

(5) ACL issued a Notice of Proposed Rulemaking (NPRM) to modify the implementing regulations of the Older Americans Act of 1965 (''the Act'' or OAA) to add a new subpart (Subpart D) related to Adult Protective Services (APS) RIN 0985–AA18. 0985–New is referenced in 88 FR 62503 pages 62503–62522 published on September 12, 2023. Comments associated with this proposed Generic Information Collection (Gen IC) should be submitted separately to the above listed program contact.

As a unit of the Administration for Community Living, the Administration on Aging (AoA) provides expertise on program development, advocacy, and initiatives for older Americans and their caregivers and families. Working with State agencies, local agencies, grantees, and community providers, AoA directs programs authorized by the OAA, Elder Justice Act (EJA), and other legislation that supports older adults. Through these programs multi-year State Plans and assurances, and other financial forms are needed to provide approval and oversight of grant recipients.

ACL is seeking OMB approval to add a new Gen IC to ACL's Paperwork inventory. This Gen IC will cover AoA formula grant programs for State Plans on Aging and assurances, State Plans on Adult Protective Services and assurances, and other financial forms associated with Aging formula grant management. Adding a Gen IC will allow for the collection of data across programmatic and financial management of the Aging and APS formula grants.

Statutory Background

In 1965, Congress originally passed the Older Americans Act (OAA) in response to concerns by policymakers about a lack of community social services for older adults. The original legislation established authority for grants to States for community planning and social services, research and development projects, and personnel training in the field of aging. Changes to the OAA were made through the Supporting Older Americans Act of 2020 (Pub. L. 116–131). This legislation reauthorized the OAA and its programs from Federal fiscal year (FFY) 2020 through 2024. The OAA provides the foundation for the National aging Network, which includes the Administration on Aging (AoA), State Units on Aging (SUA), Area Agencies on Aging (AAA), tribal organizations, service providers, and volunteers. SUAs are an integral part of the network responsible for developing and administering a multi-year State plan that advocates for and aids older residents, their families, their caregivers, and, in many States, for adults with disabilities.

The Elder Justice Act, passed in 2010, is the first comprehensive legislation to address the abuse, neglect, and exploitation of older adults at the Federal level. The law authorized a variety of programs and initiatives to better coordinate Federal responses to elder abuse, promote elder justice research and innovation, support Adult Protective Services systems, and provide additional protections for residents of long-term care facilities. The importance of these services at the State-level and local-level is demonstrated by the fact that States significantly leverage OAA funds to obtain other funding for these activities.

The Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and the American Rescue Plan Act provided two years of Federal funding ($188 million in each year) to support, for the first time, the nationwide APS formula grant program authorized by the Elder Justice Act of 2010. That funding was used by States to expand or develop a variety of capabilities that were necessary to meet increased needs due to the public health pandemic, and ongoing funding is necessary to maintain the improved reach and effectiveness of APS systems beyond the pandemic.

The FY 2023 Omnibus Appropriations Bill provided, for the first time, an annual appropriation of $15 million to continue providing Federal formula grants to State APS programs. This will be the first time State entities are required to develop and submit State plans on Adult Protective Services under Section 2042 of the Elder Justice Act, 42 U.S.C. 1397m–1(b). However, States have developed spending plans for the formula funding received to date, consistent with 45 CFR 75.206(d), and to update those every three to five years.

This new Gen IC is for programmatic and financial management of the Aging and APS formula grants. The purpose of the State Plans and assurances is to document and provide the opportunity for public comment of achievements and planned activities for the multi-year plan period. A wide range of constituents use or will use the State Plans to coordinate, monitor, evaluate, and improve Aging Network and APS support services by using the State Plans as a blueprint for service planning and delivery.

Additionally, ACL leverages State Plans to understand the numerous services older adults use, and to utilize the information for advocating for the needs of older adults and those who use APS and for requesting additional funding. The purpose of the other financial forms that are a part of this Gen IC is to facilitate OAA formula grant management.

Financial forms provide statutorily required information regarding each State's contribution to programs to ensure compliance with legislative requirements, pertinent Federal regulations, and other applicable instructions and guidelines issued by ACL. This information will be used for Federal oversight of the Aging Programs. Based on ACL's extensive experience working with APS systems and OAA grantees on their State plans, ACL does not anticipate a significantly greater level of detail for the development of State plans for APS.

Since a new Gen IC does not permit the public to examine the details of each individual collection, the ACL Generic for Administration on Aging Formula Grant Programs 0985–New Proposed Gen IC Plan can be found on the ACL website for review and comment at:

https://www.acl.gov/about-acl/public-input.

In accordance with the PRA 44 U.S.C. 3506(c)(2)(A); 44 U.S.C. 3507(a)(1)(D) ACL details the proposed Gen IC pertaining to:

- the method of collection;
- the category (or categories) of respondents;
- the estimated maximum number of burden hours (per year) for the specific information collections, and against which burden will be charged for each collection actually used;
- ACL's plans for how it will use the information collected; and
- ACL's internal procedures to ensure that the specific collections comply with the PRA, applicable regulations, and the terms of the generic clearance.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

ESTIMATED ANNUALIZED BURDEN TABLE

Respondent/data collection activity	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Unit on Aging (SUA)	State Plan on Aging	14.7	1	80	1,176
State Entity for APS	State Plan on APS	56	1	6	336
State Entity for APS	Required Assurances for APS (4)	56	3	10	1,680
State Unit on Aging (SUA)	Financial Forms	56	5	1	280
Total Estimated Burden					3,472

Dated: October 12, 2023.

Alison Barkoff,

Senior official performing the duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–22956 Filed 10–17–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–1323]

Determination That NAROPIN (Ropivacaine Hydrochloride) Solution, 50 Milligrams/10 Milliliters and 75 Milligrams/10 Milliliters, Were 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, Agency, or we) has determined that Naropin (ropivacaine hydrochloride) solution, 50 milligrams (mg)/10 milliliters (mL) and 75mg/10mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these drug products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Alexander Poonai, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Alexander.Poonai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, are the subject of NDA 020533, held by Fresenius Kabi USA LLC, and initially approved on May 1, 1998. Naropin is indicated for the production of local or regional anesthesia for surgery and for acute pain management.

Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated December 15, 2021 (Docket No. FDA–2021–P–1323), under 21 CFR 10.30, requesting that the Agency determine whether Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, were 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 Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, from sale. We have also independently