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NAROPIN (Ropivacaine Hydrochloride) Solution, 50 Milligrams/10 Milliliters and 75 Milligrams/10 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that Naropin (ropivacaine hydrochloride) solution, 50 milligrams (mg)/10 milliliters (mL) and 75mg/10mL, were not withdrawn from sale for reasons of safety or effectiveness.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

evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, 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. ANDAs that refer to Naropin (ropivacaine hydrochloride) solution, 50mg/10mL and 75mg/10mL, 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22960 Filed 10–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2986]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification

AGENCY: Food and Drug Administration, 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 November 17, 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 0910–0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Color Additive Certification

OMB Control Number 0910–0216—Extension

This information collection supports FDA regulations governing certification for color additives used in foods, drugs, cosmetics, and medical devices. All color additives must have FDA-approval for their intended use and be listed in the color additive regulations before they are permitted for use in food, drugs, cosmetics, and many medical devices. Some color additives have an additional requirement: they are permitted only if they are from batches that FDA has certified under section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)). This means that FDA chemists have analyzed a sample from the batch and have found that it meets the requirements for composition and purity stated in the regulation, called a ''listing regulation,'' for that color additive. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are established in 21 CFR part 80. Procedures for color additive certification are set forth in part 80, subpart B (§§ 80.21 through 80.39) and communicate required data elements for requests for certification, limitations of certificates, exemptions from certification for color additive mixtures, treatment of batches pending and after certification, and recordkeeping requirements for respondents to whom a certificate is issued. During the batch certification procedure, a manufacturer of color additives must submit a ''request for certification'' that provides information about the batch, accompanied by a representative sample of a new batch of color additive, to FDA's Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate that contains a certification lot number for the batch. The batch can then be used in FDA-regulated products marketed in the United States, in compliance with the uses and restrictions in that color additive's listing regulation. If the sample does not meet the requirements, the batch will be rejected. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

FDA's web-based color certification information system is available for respondents to request color certification online, track their submissions, and obtain account status information. Prior to submitting a request for certification, the manufacturer must open a color certification account by sending a letter, as an email attachment, signed by responsible company representative, to FDA's Office of Cosmetics and Colors at *color.cert@fda.hhs.gov.* System certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates.

We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification. The user fees support FDA's color certification program. Additional information about color additive certification is available at: *https://www.fda.gov/industry/color-additives/color-certification.*

The purpose for collecting this information is to help the Agency assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States.

Description of Respondents: The respondents include businesses engaged in the manufacture of color additives used in FDA-regulated foods, drugs, cosmetics, and medical devices. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of August 10, 2023 (88 FR 54329), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.