www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Generally Accepted Scientific Knowledge in Applications for Drugs and Biological Products: Nonclinical Information.'' This guidance describes two types of instances in which it may be appropriate to rely on GASK to meet certain nonclinical safety requirements for NDAs and BLAs, regardless of regulatory pathway for approval or licensure (*e.g.,* an NDA under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)) or an NDA pursuant to section 505(b)(2) of the FD&C Act; or a BLA under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) or a BLA under section 351(k) of the PHS Act). The information that supports the nonclinical safety of a drug or biological product and that must be submitted in the application can include references to GASK, when appropriate, instead of or in addition to, specific studies conducted with respect to the drug or biological product. In such cases, therefore, it might be unnecessary to conduct certain nonclinical studies. This guidance does not address the use of GASK in other contexts (*e.g.,* clinical studies).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312, investigational new drug applications, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314, NDAs and abbreviated new drug applications, have been approved under OMB control number 0910–0001, and the collections of information in 21 CFR part 601, BLAs, have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11148 Filed 5–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–3293]

Determination That Chirocaine (Levobupivacaine) Injection, 2.5 Milligrams (Base)/Milliliter, 10 Milliliter and 30 Milliliter Vials, 5 Milligrams (Base)/Milliliter, 10 Milliliter and 30 Milliliter Vials and 7.5 Milligrams (Base)/Milliliter, 10 Milliliter and 30 Milliliter Vials, 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 or Agency) has determined that Chirocaine (levobupivacaine) injection, 2.5 milligrams (mg) (base)/milliliter (mL), 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for levobupivacaine injection, 2.5 milligrams (mg) (base)/milliliter (mL), 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Donna Tran, 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, *Donna.Tran@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.

Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, is the subject of NDA 020997, held by Purdue Pharma L.P., and initially approved on August 5, 1999. Chirocaine is indicated to produce local or regional anesthesia for surgery and obstetrics, and for post-operative pain management.

In a letter dated May 21, 2004, Purdue Pharma L.P. requested withdrawal of NDA 020997 for Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials. In the **Federal Register** of March 4, 2005 (70 FR 10651), FDA announced that it was withdrawing approval of NDA 020997, effective April 4, 2005. Chirocaine is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated December 21, 2022 (Docket No. FDA–2022–P–3293), under 21 CFR 10.30, requesting that the Agency determine whether Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, were withdrawn from sale for reasons of safety or efficacy.

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 Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, were withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, 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 Chirocaine (levobupivacaine) injection, 2.5 mg (base)/mL, 10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials or 7.5 mg (base)/mL, 10 mL and 30 mL vials, 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: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11162 Filed 5–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a generic collection of information through which we intend to seek insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services.

DATES: Either electronic or written comments on the collection of information must be submitted by July 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 comment will be made public, you are solely responsible for ensuring that your