access to records (5 CFR part 2606). In addition, individuals seeking access to records filed with the DAEO at the agency where the employee beneficiary is employed must follow that agency's regulations regarding verification of identity and access to records.

CONTESTING RECORD PROCEDURES:

Because the information in these records is updated on a periodic basis, most record corrections can be handled through internal agency procedures for updating the records without the need for a formal request to amend pursuant to the Privacy Act. However, individuals can obtain information on the procedures for contesting the records under the provisions of the Privacy Act by contacting the appropriate office shown in the Notification Procedure section.

Individuals requesting records corrections of records maintained at OGE must also follow OGE's Privacy Act regulations regarding verification of identity and access to records (5 CFR part 2606). In addition, individuals requesting corrections to records filed with the DAEO at the agency where the employee beneficiary is employed must follow that agency's regulations regarding verification of identity and access to records.

NOTIFICATION PROCEDURES:

Individuals wishing to inquire whether this system of records contains information about them should contact, as appropriate:

a. For records filed directly with OGE, contact the General Counsel, Office of Government Ethics, Suite 500, 1201 New York Avenue NW, Washington, DC 20005–3917; and

b. For records filed with the DAEO where the employee beneficiary is employed, contact the DAEO at the department or agency concerned.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Approved: May 10, 2023.

Emory Rounds,

Director, U.S. Office of Government Ethics.

[FR Doc. 2023–10292 Filed 5–24–23; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1618]

Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Generally Accepted Scientific Knowledge in Applications for Drug and Biological Products: Nonclinical Information.'' This draft guidance is intended to assist sponsors in determining whether it may be appropriate to rely on generally accepted scientific knowledge (GASK) to fulfill certain legal and regulatory requirements applicable to the new drug application (NDA) or biologics licensing application (BLA) in question. When final, this guidance will represent the Agency's current thinking on this topic.

DATES: Submit either electronic or written comments on the draft guidance by July 24, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–1618 for ''Generally Accepted Scientific Knowledge in Applications for Drugs and Biological Products: Nonclinical Information.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*

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]

BILLING CODE 4164–01–P

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