Dated: November 17, 2023.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–4223]

Determination That BUPRENEX (Buprenorphine Hydrochloride) Injection, 0.3 Milligram/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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, the Agency, or we) has determined that BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 milligram (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness.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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993–0002, 301–796–3600, *Caitlin.Callahan@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is the subject of NDA 018401, held by Indivior, Inc., and initially approved on December 29, 1981. BUPRENEX is indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Odin Pharmaceuticals LLC submitted a citizen petition dated September 27, 2023 (Docket No. FDA–2023–P–4223), under 21 CFR 10.30, requesting that the Agency determine whether BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, 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 BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, 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 this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list BUPRENEX (buprenorphine hydrochloride) Injection, 0.3 mg/mL, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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.

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25857 Filed 11–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4719]

Translation of Good Laboratory Practice Study Reports: Questions and Answers; 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 ''Translation of GLP Study Reports: Questions and Answers.'' This guidance provides information to sponsors and nonclinical laboratories regarding the translation of study reports for studies conducted in compliance with good laboratory practice (GLP) regulations. GLP studies are nonclinical safety studies that include, but are not limited to nonclinical toxicology studies, safety pharmacology studies, and device safety studies. When study reports of GLP studies are translated from the original language into English, adequate documentation is critical to ensure

accurate and complete study data are submitted to FDA. This question-and-answer document is intended to clarify FDA's recommendations concerning the translation of GLP study reports from a non-English language into English for nonclinical studies conducted in compliance with GLP regulations.

DATES: Submit either electronic or written comments on the draft guidance by February 20, 2024 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–4719 for ''Translation of GLP Study Reports: Questions and Answers.'' 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 to the 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: Tahseen Mirza, Center for Drug Evaluation and Research, Office of Study Integrity and Surveillance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993, 301–796–7645; Anne Taylor, Office of the Center Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Judith Davis, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993, 301–796–6636; Tong Zhou, Center for Veterinary Medicine, Office of New Animal Drug Evaluation, HFV–153, Food and Drug Administration, 7500 Standish Place, Rockville, MD, 20855, 240–402–0826; Yuguang Wang, Center for Food Safety and Applied Nutrition, Office of the Center Director, Food and Drug Administration, 5001 Campus Dr., Rm. 4A035, College Park, MD, 20740, 240-402–1757; Hans Rosenfeldt, Center for Tobacco Products, Office of Science, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 301–796–1327; Darby Hull, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857, 301–796–5949.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Translation of GLP Study Reports: Questions and Answers.'' Nonclinical laboratory studies conducted in compliance with GLP regulations (21 CFR part 58) are being conducted by testing facilities located in foreign countries. In instances where the GLP study report is generated in a non-English language, the study report is often translated into English for submission to FDA. When translating a study report into English from a study conducted in compliance with GLP regulations, the translation should be clear, accurate, complete, and follow written processes and procedures. The sponsor should ensure that the

translated report is an accurate representation of the original GLP study report.

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 ''Translation of GLP Study Reports: Questions and Answers.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 58 for good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

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.regulations.gov,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: November 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4996]

Advancing Drug Development for the Prevention of Spontaneous Preterm Birth; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Advancing Drug Development for the Prevention of Spontaneous Preterm Birth.'' The meeting will be convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting is intended to gather industry, family, clinician, researcher, ethicist, professional society, and other stakeholder input on the impact of preterm birth on families and on society, as well as on the ethical, regulatory, and clinical trial considerations surrounding the drug development for the prevention of spontaneous preterm birth.

DATES: The public meeting will be held on January 23 and 24, 2024, from 1 p.m. to 4:30 p.m. Eastern Time each day. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held virtually via Zoom.

FOR FURTHER INFORMATION CONTACT: Luke Durocher, Duke-Margolis Center for Health Policy, *margolisevents@duke.edu,* 202–621–2800; or Christina Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2078.

SUPPLEMENTARY INFORMATION:

I. Background Information

In the United States in 2021, 1 in every 10 infants was born prematurely (before 37 weeks of pregnancy). Infants born too early have higher rates of death and disability, resulting in a significant public health concern. The exact mechanisms and risk factors associated with spontaneous preterm birth are not fully understood, resulting in a dearth of interventions demonstrated to be effective and safe.

FDA endorses an informed and balanced approach to gathering data supporting the safe and effective use of drugs and biological products for the prevention of spontaneous preterm birth. Currently, there is a significant medical need for such therapies, as there are no FDA approved therapies for reducing the risk of neonatal morbidity/mortality resulting from spontaneous preterm birth. Input from this meeting will help provide guidance on the development of therapies for the prevention of spontaneous preterm birth.

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including clinicians, patients, family, researchers, ethicists, professional societies, and other stakeholders) to provide input on key topics, including:

- The current understanding of spontaneous preterm birth, including the epidemiology of the condition, etiologies, and pathophysiology
- Ethical and regulatory considerations and challenges associated with the development of therapeutics for the prevention of spontaneous preterm birth
- Impact of preterm birth on families and society
- Assessing efficacy and safety in clinical programs for therapeutics for spontaneous preterm birth prevention
- Dose-finding and clinical trial design considerations

For more information on the meeting topics and discussion questions, visit *https://duke.is/g/gde6.* Duke-Margolis will publish a discussion guide outlining background information and current thinking on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the virtual public meeting, please visit the following website: *https://duke.is/g/gde6.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this virtual public meeting must register. Early registration is recommended. Registrants will receive confirmation once they have been accepted. If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, at *margolisevents@duke.edu* or at 202–621–2800.

Streaming Webcast of the Public Meeting: This virtual public meeting will be webcast via Zoom and the archived video footage will be available at the event website. The link for registration is the same as above: *https://duke.is/g/gde6.* Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.