Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15609 Filed 7–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–1248]

Determination That XYLOCAINE (Lidocaine Hydrochloride) Topical Solution 4%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that XYLOCAINE (lidocaine hydrochloride), Topical Solution 4%, was not withdrawn from sale for reasons of safety or effectiveness.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: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6258, Silver Spring, MD 20993–0002, 301–796–8767, *David.Faranda@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 FDA's approval of 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.

XYLOCAINE (lidocaine hydrochloride) Topical Solution 4%, is the subject of NDA 010417, held by Fresenius Kabi USA, LLC, and initially approved on May 7, 1959. XYLOCAINE is indicated for the production of topical anesthesia of the mucous membranes of the respiratory tract or the genito-urinary tract.

In a letter dated January 29, 2018, Fresenius Kabi USA, LLC, requested that FDA withdraw approval of NDA 010417 for XYLOCAINE (lidocaine hydrochloride). In the **Federal Register** of October 29, 2018 (83 FR 54355 at 54356), FDA announced that it was withdrawing approval of NDA 010417 as of November 28, 2018. This product is identified as discontinued in the Orange Book.

Lyne Laboratories, Inc., submitted a citizen petition dated December 2, 2021 (Docket No. FDA–2021–P–1248), under 21 CFR 10.30, requesting that the Agency determine whether XYLOCAINE (lidocaine hydrochloride) Topical Solution 4%, 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 XYLOCAINE (lidocaine hydrochloride) Topical Solution 4%, 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 XYLOCAINE (lidocaine hydrochloride) Topical Solution 4 percent, 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 XYLOCAINE (lidocaine hydrochloride) Topical Solution 4%, 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: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15594 Filed 7–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0219]

Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—''Dose Banding''; 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 ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—'Dose Banding'.'' The guidance is intended to assist applicants in incorporating dose banding information into the drug

labeling provided in a new drug application (NDA) submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act), a biologics license application (BLA) submitted under the Public Health Service Act (PHS Act), or a supplement to one of these approved applications when an applicant proposes to develop ready-to-use containers with a range of different strengths and seeks to incorporate dose banding information into the prescribing information of the proposed drug product based on dosing information of a previously approved drug product that is based on weight or body surface area (BSA).

DATES: Submit either electronic or written comments on the draft guidance by September 19, 2022 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–2022–D–0219 for ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—'Dose Banding'.'' 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 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: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–0151; or Stephen Ripley 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 ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—'Dose Banding'.'' This guidance provides recommendations for incorporating dose banding information into the drug labeling of an NDA submitted under section 505(b) of the FD&C Act (21 U.S.C. 355(b)), a BLA submitted under section 351(a) of the PHS Act (42 U.S.C. 262(a)), or a supplement to one of these approved applications. The recommendations and examples in this guidance apply when an applicant (1) proposes to develop ready-to-use containers with a range of different strengths and (2) seeks to incorporate dose banding information into the prescribing information of the proposed drug product based on dosing information of a previously approved drug product that is based on weight or BSA.

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 ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use

Containers—'Dose Banding'.'' 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 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 201 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 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: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15523 Filed 7–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–xxxx–New]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, as described below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than September 19, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Healthy Start Evaluation and Capacity Building Support, OMB No. 0906–xxxx–New.

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (§ 330H of the Public Health Service Act) and funded through HRSA's Maternal and Child Health Bureau, has the goal of reducing disparities in maternal and infant health. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 3 decades to 101 grantees across 35 states, Washington, DC, and Puerto Rico. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average, or with high rates of other adverse perinatal outcomes (*e.g.,* low birthweight, preterm birth). Grantees may also qualify for the program if their project areas meet other relevant criteria (*e.g.,* high rates of diabetes, obesity, or tobacco use during pregnancy; low utilization of prenatal care in the first trimester; no utilization of prenatal care during pregnancy) that demonstrate disparities in health outcomes for pregnant women in their communities. Healthy Start programs are located in communities that are geographically, racially, ethnically, and linguistically diverse. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the women, infants, and fathers/partners through 18 months after the end of the pregnancy. The Healthy Start program uses a life course approach that includes women's health, family health and wellness, and community/population health.

HRSA seeks to implement a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include the (1) Healthy Start Program Survey, (2) Healthy Start Network Survey, (3) Healthy Start Participant Survey, and (4) Healthy Start Stakeholder Interview Guide. These instruments have been specifically designed to be non-duplicative. Using previously approved content, the Healthy Start Program Survey is designed to collect information on the experiences of all 101 grantee programs related to program infrastructure, services/activities, participants, community partnerships, new maternal and fatherhood initiatives, and health equity. The information collected in the survey will allow the Healthy Start grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

The two other surveys and interview guide will be administered to a subset of 15 grantees, their community partners, and participants. The Healthy Start Network Survey focuses on understanding the participation of members in the Healthy Start Community Action Networks (CANs) [1] and collaborations within the CANs to improve maternal, infant, and family outcomes within the Healthy Start communities. Results from the survey will help the Healthy Start programs and their CANs identify areas of strength and opportunities for further collaborations, understand how well the CAN members are working together to serve women and their families, and whether they are supporting the programs in addressing the participants' greatest needs. The Healthy Start Participant Survey is designed to collect information about the experiences of the Healthy Start participants with the program and assess whether the programs are meeting their needs. The Healthy Start grantees can use this

[1] A CAN is an existing, formally organized partnership of organizations and individuals. The CAN represents consumers and appropriate agencies which unite in an effort to collectively apply their resources to the implementation of one or more common strategies to achieve a common goal within that project area.