

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-0608]

Development of Local Anesthetic Drug Products With Prolonged Duration of Effect; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Development of Local Anesthetic Drug Products With Prolonged Duration of Effect.” The draft guidance reflects the Agency’s current recommendations regarding drug development and trial design issues relevant to the study of local anesthetic drug products with prolonged duration of effect for which submission of a new drug application (NDA) is planned. The recommendations in the guidance are intended to assist developers in generating the data necessary to support different indications and labeling claims for these drugs.

DATES: Submit either electronic or written comments on the draft guidance by June 14, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-0608 for “Development of Local Anesthetic Drug Products With Prolonged Duration of Effect.” 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 this 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. 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:

Swati Patwardhan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3242, Silver Spring, MD 20993-0002, 301-796-4085, swati.patwardhan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Development of Local Anesthetic Drug Products With Prolonged Duration of Effect.” The draft guidance provides recommendations to assist sponsors in the development of local anesthetic drug products with prolonged duration of effect for which submission of an NDA is planned. The guidance focuses on trial design considerations and pharmacokinetic, safety, and efficacy data necessary to support different indications for local anesthetic drug products with prolonged duration of effect.

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 “Development of Local Anesthetic Drug Products With Prolonged Duration of Effect.” 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 relating to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 201 relating to prescription product labeling requirements have been approved under OMB control number 0910–0572.

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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05396 Filed 3–15–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher.

FDA has determined that SKYCLARYS (omaveloxolone), approved February 28, 2023, and manufactured by Reata Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: Cathryn.Lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that SKYCLARYS (omaveloxolone), manufactured by Reata Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

SKYCLARYS (omaveloxolone) capsule is for the treatment of Friedreich’s ataxia in adults and adolescents aged 16 years and older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about SKYCLARYS (omaveloxolone), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05364 Filed 3–15–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Request for Nominations From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Blood Products Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Blood Products Advisory Committee (BPAC) for the Center for Biologics Evaluation and Research notify FDA in writing. FDA is also requesting nominations for a nonvoting industry representative(s) to serve on the BPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by April 17, 2023 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by April 17, 2023.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent via email to Christina Vert (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives must be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA’s website at: <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT:

Christina Vert or Marie DeGregorio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, email: CBERBPAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative(s) to the following advisory committee:

I. Blood Products Advisory Committee

BPAC reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology that are