Silver Spring, MD 20993, 301–796–3473, *Elimika.Fletcher@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products.'' Effectiveness, safety, or dose-finding studies in pediatric patients involve gathering clinical pharmacology information, such as information regarding a product's pharmacokinetics and pharmacodynamics, to inform dose selection and individualization. This draft guidance addresses general clinical pharmacology considerations for conducting studies so that the dosing and safety information for drugs and biological products in pediatric populations can be sufficiently characterized, leading to well-designed trials to evaluate effectiveness.

In general, this draft guidance focuses on the clinical pharmacology information (*e.g.,* exposure-response, pharmacokinetics, and pharmacodynamics) that supports findings of effectiveness and safety and helps identify appropriate doses in pediatric populations. This draft guidance also describes how quantitative approaches (*i.e.,* pharmacometrics) can use disease and exposure-response knowledge from relevant prior clinical studies to help design and evaluate future pediatric studies.

This draft guidance revises the draft guidance, ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products,'' issued on December 9, 2014 (79 FR 73079). This draft guidance provides clarification on clinical pharmacology studies in pediatric patients from the 2014 draft guidance in response to public comments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products.'' 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

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information for the submission of new drug applications in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information for the submission of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information for the submission of investigational new drug applications in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information for the protection of human subjects and institutional review boards in parts 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information for the submission of prescription drug product labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR 312.47 and 312.82 for requesting meetings with FDA about drug development programs have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19410 Filed 9–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (the 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 issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that VABYSMO (faricimab-svoa), for which a priority review voucher was redeemed, was approved January 28, 2022.

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 approval of product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that VABYSMO (faricimab-svoa), approved January 28, 2022, meets the redemption criteria.

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 VABYSMO (faricimab-svoa), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: August 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19384 Filed 9–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: October 3, 2022.

Time: 1:00 p.m. to 5:00 p.m. EDT.

Agenda: The purpose of this meeting is to bring together committee members, representing government agencies, patient advocacy groups, other voluntary health organizations, and patients and their families to update one another on progress relevant to the Action Plan for the Muscular Dystrophies and to coordinate activities and discuss gaps and opportunities leading to better understanding of the muscular dystrophies, advances in treatments, and improvements in patients' and their families' lives. The agenda for this meeting will be available on the MDCC website: *https://www.mdcc.nih.gov/.*

Registration: To register, please go to: *https://roseliassociates.zoomgov.com/webinar/register/WN_ZAC101DzRVy7jcFHmIIIJw.*

Webcast Live: https://videocast.nih.gov/.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Glen Nuckolls, Ph.D., Program Director, National Institute of Neurological, Disorders and Stroke (NINDS), NIH, 6001 Executive Blvd., Rm 2203, Bethesda, MD 20892, 301–496–5876, *MDCC@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

More information can be found on the Muscular Dystrophy Coordinating Committee home page: *https://mdcc.nih.gov/.*

Dated: September 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–19381 Filed 9–7–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; NIA Multi-site Clinical Trial Implementation.

Date: October 11, 2022.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *MIKHAILI@MAIL.NIH.GOV.*

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–19380 Filed 9–7–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Review of SuRE applications.

Date: November 4, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Science, Natcher Bldg. 45, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Saraswathy Seetharam, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301–594–2763, *seetharams@nigms.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: September 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–19379 Filed 9–7–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; PPG Review SEP.

Date: October 11, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).