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FDA is announcing the availability of a revised draft guidance for industry entitled ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products.''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 This draft guidance addresses general clinical pharmacology considerations for conducting studies so that the dosing and safety information for drugs and biological products in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In general, this draft guidance focuses on the clinical pharmacology information (*e.g.,* exposure-response, pharmacokinetics, and pharmacodynamics) that supports findings of effectiveness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 This draft guidance also describes how quantitative approaches (*i.e.,* pharmacometrics) can use disease and exposure-response knowledge from relevant prior clinical studies to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This draft guidance revises the draft guidance, ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products,'' issued on December 9, 2014 (79 FR 73079). This draft guidance provides clarification on clinical pharmacology studies in pediatric patients from the 2014 draft guidance in response to public comments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological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This draft guidance refers to previously approved FDA collections of information.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