

See https://www.ssa.gov/OP_Home/ssact/title05/0510.htm.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–19231 Filed 9–6–22; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2029]

Proposal To Withdraw Approval of MAKENA; Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of hearing; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Proposal To Withdraw Approval of MAKENA; Hearing” that appeared in the **Federal Register** of August 17, 2022. The document announced the hearing on the Center for Drug Evaluation and Research’s proposal to withdraw approval of MAKENA (hydroxyprogesterone caproate injection, 250 milligrams per milliliter, once weekly), new drug application 021945, held by Covis Pharma Group/Covis Pharma GmbH. The document was published with an incorrect deadline. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931, rachael.linowes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 17, 2022 (87 FR 50626), in FR Doc. 2022–17715, on page 50628, the following correction is made:

1. On page 50628, in the last paragraph of the second column, in the first sentence, “September 6, 2022” is corrected to “September 14, 2022.”

Dated: September 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19293 Filed 9–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

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 ZTALMY (ganaxolone), manufactured by Marinus 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 ZTALMY (ganaxolone), manufactured by Marinus Pharmaceuticals, Inc., meets the criteria for a priority review voucher. ZTALMY (ganaxolone) is indicated to treat seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in patients 2 years of age 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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ZTALMY (ganaxolone), 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. 2022–19276 Filed 9–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Commission on Childhood Vaccines

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Commission on Childhood Vaccines (ACCV). The ACCV advises the Secretary of HHS (Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP). HRSA is seeking nominations of qualified candidates to fill vacancies on the ACCV.

DATES: Written nominations for membership on the ACCV will be received on a continuous basis.

ADDRESSES: Nomination packages must be submitted to the Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857. Candidates can submit electronic nomination packages by email to Pita Gomez at ACCV@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, Health Systems Bureau, HRSA at (301) 945–9386 or email at ACCV@hrsa.gov. A copy of the ACCV charter and list of the current membership is available on the ACCV website at <https://www.hrsa.gov/advisory-committees/vaccines/index.html>.

SUPPLEMENTARY INFORMATION: The ACCV was established by Title XXI of the Public Health Service Act (the Act) and advises the Secretary on issues related to implementation of the VICP. The ACCV meets at least four times each calendar year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the ACCV to fill open positions. The Secretary appoints members with the expertise needed to fulfill the duties of the ACCV. The