

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]

BILLING CODE 4164–01–P

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

membership requirements are set forth in section 2119 of the National Childhood Vaccine Injury Act.

The ACCV consists of nine voting members appointed by the Secretary as follows: (1) Three health professionals, who are not employees of the U.S. government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians; (2) three members from the general public, of whom at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and (3) three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as non-voting ex officio members.

HHS will consider nominations of all qualified individuals with a view to ensure that the ACCV includes the areas of subject matter expertise noted above. As indicated above, at least two of the three ACCV members of the general public must be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death. Because those members must be the legal representatives of children who have suffered a vaccine-related injury or death, to be considered for appointment to the ACCV in that category, there must have been a finding (*i.e.*, a decision) by the U.S. Court of Federal Claims or a civil court that a VICP-covered vaccine caused, or was presumed to have caused, the represented child's injury or death. Additionally, based on a recommendation made by the ACCV, the Secretary will consider having a health professional with expertise in obstetrics as one of the members of the general public. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the Committee will be invited to serve for up to 3 years. Members are appointed as SGEs and receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACCV meetings and/or conducting other

business on behalf of the ACCV, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) a letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the ACCV) and the nominee's field(s) of expertise; (2) the name, address, daytime telephone number, and email address at which the nominator can be contacted; and (3) a current copy of the nominee's curriculum vitae. The individual being nominated or the person/organization recommending the candidate may submit nomination packages directly to HRSA, which will collect and retain nomination packages to create a pool of possible future ACCV voting members. When a vacancy occurs, HRSA and HHS will review nomination packages from the appropriate category and nominees may be contacted at that time.

HHS endeavors to ensure that the membership of the ACCV is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of race, age, ethnicity, national origin, gender, disability, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of the ACCV and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463) and section 2119 of the National Childhood Vaccine Injury Act (Pub. L. 99-660, as amended), HRSA is requesting

nominations for voting members of the ACCV.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022-19242 Filed 9-6-22; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Ritankar Majumdar, Ph.D. (Respondent), who was a postdoctoral fellow in the intramural program of the Laboratory of Cellular and Molecular Biology (CMB), Center for Cancer Research (CCR), National Cancer Institute (NCI), National Institutes of Health (NIH). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically the NCI Intramural Research Program. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on August 15, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr.P.H., Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Ritankar Majumdar, Ph.D., National Institutes of Health: Based on the report of an investigation conducted by NIH and analysis conducted by ORI in its oversight review, ORI found that Dr. Ritankar Majumdar, former postdoctoral fellow in the intramural program of the Laboratory of CMB, CCR, NCI, NIH, engaged in research misconduct in research supported by PHS funds, specifically the NCI Intramural Research Program.

ORI found that Respondent engaged in research misconduct by knowingly or recklessly falsifying and/or fabricating data in the following one (1) published paper, one (1) manuscript, three (3) PHS grant applications, and fifteen (15) presentations:

- Exosomes Mediate LTB4 Release during Neutrophil Chemotaxis. *PLoS Biol.* 2016 Jan 7; 14(1):e1002336; doi: 10.1371/journal.pbio.1002336 (hereafter referred to as "*PLoS Biol* 2016").