Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–19256 Filed 9–6–22; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Sexual Risk Avoidance Education National Evaluation: Nationwide Study of the National Descriptive Study (New Collection)

AGENCY: Office of Planning, Research and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), proposes survey and focus group data collection activities for the Sexual Risk Avoidance Education National Evaluation (SRAENE) Nationwide Study (NWS) of the National Descriptive Study (NDS).

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review-Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OPRE/ACF/HHS proposes to conduct the NWS, a sub-study under the NDS of the SRAENE, to learn about Sexual Risk Avoidance Education (SRAE) program implementation experiences and outcomes of the SRAE grant program. The NWS builds on the Early Implementation Study, the first sub-study of the NDS, which was designed to tell the story about SRAE grant program plans (OMB Control #0970–0530). The NWS, which responds to Congress's reauthorization in February 2018 of title V, section 510 of the Social Security Act (Pub. L. 115–123), extended by the CARES ACT of 2020 (Pub. L. 116–136), will use a mixed-methods approach of surveys and focus groups to tell the story of the SRAE grant program, collecting detailed information on grantee program implementation experiences from grant recipients, SRAE program providers and facilitators, and youth program recipients. The NWS will also make use of extant data from grant-recipient performance measures on program outputs and outcomes. Combined with data on program implementation, the NWS will examine associations between implementation, outputs, and outcomes. The survey and focus group data are key to fully understanding program implementation experiences from all levels that bring the SRAE programs to youth-from grant administrators to program supervisors to the facilitators who interact directly with the youth themselves.

The study is being undertaken by ACF and its contractor Mathematica. The study research questions driving the need for data collection are as follows:

1. What are grant recipients' and providers' experiences with delivering SRAE curricular content? What are youth's experiences with receiving the SRAE curricular content?

2. How did grant recipients and providers interpret, understand, and address the A to F topics in the SRAE legislation?

3. Are some features of implementation more strongly associated with youth outcomes than others?

4. What provider characteristics are associated with a greater number of youth served and with youth outcomes?

To support these efforts, ACF proposes the following data collection activities: (1) a web-based survey of all grant recipient Directors who are not also providers, (2) a web-based survey of all SRAE program providers, (3) a web-based survey of all SRAE program facilitators, and (4) in-person (or virtual if necessary) focus groups with youth recipients of SRAE programming across five geographic regions of the United States.

Respondents: Respondents to the surveys will be SRAE program grant Directors, SRAE program providers, and SRAE program facilitators. Focus group participants will be youth recipients of SRAE programming. The focus group participants will be recruited from middle and high school across five U.S. Geographic regions: West, Midwest, Southwest, Southeast, and Northeast.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
(1) NWS Grantee Survey	40	1	.17	7
(2) NWS Provider Survey	500	1	.75	375
(3) NWS Facilitator Survey	1,600	1	.75	1,200
(4) SRAE Program Youth Focus Group Discussion Guide	200	1	* .83	166
Estimated Total Annual Burden Hours:				1,748

* Average burden per response includes 5 minutes to complete the consent and assent forms.

Authority: The Title V Competitive SRAE Program was authorized and funded by section 510 of the Social Security Act (42 U.S.C. 710), as amended by section 50502 of the Bipartisan Budget Act of 2018 (Public Law 115–123) and extended by the CARES Act of 2020 (Public Law 116–136).

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]

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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/DevelopingProductsforRareDiseasesConditions/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