authorized new optional title IV–E funding for time-limited (one year) prevention services for mental health/substance abuse and in-home parent skill-based programs for: (1) A child who is a candidate for foster care (as defined in section 475(13) of the Act), (2) pregnant/parenting foster youth, and (3) the parents/kin caregivers of those children and youth (sections 471(e), 474(a)(6), and 475(13) of the Act). Title IV–E prevention services must be rated as promising, supported, or well-supported in accordance with HHS criteria and be approved by HHS (section 471(e)(4)(C) of the Act) as part of the title IV–E Prevention Services Clearinghouse (section 476(d)(2) of the Act). A state or tribal title IV–E agency electing to participate in the program must submit a 5-year title IV–E prevention program plan that meets the statutory requirements. (See Program Instructions ACYF–CB–PI–18–09 and ACYF–CB–PI–18–10 for more information.)

The FFPSA also amended Section 474(a)(7) of the Act to reimburse state and tribal IV–E agencies for a portion of the costs of operating kinship navigator programs that meet certain criteria. To qualify for funding under the title IV–E Kinship Navigator Program, the program must meet the requirements of a kinship navigator program described in section 427(a)(1) of the Act. The Kinship Navigator Program must also meet practice criteria of promising, supported, or well-supported in accordance with HHS criteria and be approved by HHS (section 471(e)(4)(C) of the Act). To begin participation in the title IV–E Kinship Navigator Program, a title IV–E agency must submit an attachment to its title IV–E plan that specifies the kinship navigator model it has chosen to implement and, the date on which the provision of program services began or will begin, and that provides an assurance that the model meets the requirements of section 427(a)(1) of the Act, as well as a brief narrative describing how the program will be operated. (Please see Program Instruction ACYF–CB–PI–18–11 for additional information.)

Respondents: State and tribal title IV–E agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total Number of Respondents	Number of Responses Per Respondent	Average Burden Hours Per Response	Annual Burden Hours
Title IV–E Prevention Services Plan	30	1	5	150
Attachment to Title IV–E plan for Kinship Navigator Program	45	1	1	45

Estimated Total Annual Burden Hours: 195.

Authority: Title IV–E of the Social Security Act as amended by Public Law 115–123 enacted February 9, 2018.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure 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 material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that JYNNEOS, (Smallpox and Monkeypox Vaccine, Live, Non-replicating), manufactured by Bavarian Nordic A/S, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating), manufactured by Bavarian Nordic A/S, meets the criteria for a material threat MCM priority review voucher because it is intended to prevent smallpox infection and meets the other criteria for a material threat MCM priority review voucher. JYNNEOS is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating), go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at *https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products.*

Dated: October 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21984 Filed 10–8–19; 8:45 am]

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