

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

(Type of) respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Smokers, ages 18–54, in the United States.	Smoker Survey Wave A (English)	2,587	1	20/60
	Smoker Survey Wave A (Spanish)	80	1	20/60
	Smoker Survey Wave B (English)	1,617	1	20/60
	Smoker Survey Wave B (Spanish)	50	1	20/60
	Smoker Survey Wave C (English)	1,617	1	20/60
	Smoker Survey Wave C (Spanish)	50	1	20/60
	Smoker Survey Wave D (English)	1,617	1	20/60
	Smoker Survey Wave D (Spanish)	50	1	20/60
	Smoker Survey Wave E (English)	1,617	1	20/60
	Smoker Survey Wave E (Spanish)	50	1	20/60
	Smoker Survey Wave F (English)	1,617	1	20/60
	Smoker Survey Wave F (Spanish)	50	1	20/60
	Smoker Survey Wave G (English)	1,617	1	20/60
	Smoker Survey Wave G (Spanish)	50	1	20/60
	Smoker Survey Wave H (English)	1,617	1	20/60
	Smoker Survey Wave H (Spanish)	50	1	20/60
	Adult Nonsmokers, ages 18–54, in the United States.	Smoker Survey Wave I (English)	1,617	1
Smoker Survey Wave I (Spanish)		50	1	20/60
Nonsmoker Survey Wave A (English)		1,000	1	20/60
Nonsmoker Survey Wave A (Spanish)		100	1	20/60
Nonsmoker Survey Wave B (English)		808	1	20/60
Nonsmoker Survey Wave B (Spanish)		25	1	20/60
Nonsmoker Survey Wave C (English)		808	1	20/60
Nonsmoker Survey Wave C (Spanish)		25	1	20/60
Nonsmoker Survey Wave D (English)		808	1	20/60
Nonsmoker Survey Wave D (Spanish)		25	1	20/60
Nonsmoker Survey Wave E (English)		808	1	20/60
Nonsmoker Survey Wave E (Spanish)		25	1	20/60
Nonsmoker Survey Wave F (English)		808	1	20/60
Nonsmoker Survey Wave F (Spanish)		25	1	20/60
Nonsmoker Survey Wave G (English)		808	1	20/60
Nonsmoker Survey Wave G (Spanish)		25	1	20/60
Nonsmoker Survey Wave H (English)		808	1	20/60
Nonsmoker Survey Wave H (Spanish)	25	1	20/60	
Nonsmoker Survey Wave I (English)	808	1	20/60	
Nonsmoker Survey Wave I (Spanish)	25	1	20/60	

Jeffrey M. Zirger,

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Office of Scientific Integrity, Office of Science,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Plan for Foster Care and Adoption Assistance—Title IV–E (OMB #0970–0433)

AGENCY: Children’s Bureau; Administration for Children and Families; the Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: Public Law 115–123 added two new programs to title IV–E of the Social Security Act: The Prevention Services Program and the Kinship Navigator Program. Title IV–E agencies will be required to report information regarding these programs in title IV–E plans. Therefore, the Administration for Children and Families (ACF) is requesting to revise the existing information collection Plan for Foster Care and Adoption Assistance (OMB #0970–0433) to include two new information collections specific to these two new programs.

DATES: *Comments due within 30 days of publication.* Office of Management and Budget (OMB) is required to make a decision concerning 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION: Title IV–E of the Social Security Act (the Act) was amended by Public Law 115–123, which included the Family First Prevention Services Act (FFPSA). The FFPSA

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.
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