

genitalium. These data may inform future CDC STD Treatment Guidelines.

There are an estimated 100 respondents (anticipated to report once per year) who will be clinicians in private and public health care settings. The data collection is necessary as there are no current national

recommendations for patients who fail current CDC-recommended therapy for *M. genitalium*. Each case report form is anticipated to take up to 60 minutes to complete.

This data collection provides CDC with information to determine which second-line treatments are most

clinically effective, as well as determining antibiotic resistance patterns of *M. genitalium* throughout the US. There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 100 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Physician or Nurse Practitioner.	M. genitalium Treatment Failure Registry Case Report Form.	100	1	1	100

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Generic Clearance for the Comprehensive Child Welfare Information System (CCWIS) Review and Technical Assistance Process (New Collection)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to establish a generic clearance to collect information to assess regulatory requirements of title IV-E agencies' Comprehensive Child Welfare Information System (CCWIS)

and ensure that the CCWIS is utilized for purposes consistent with the efficient, economical, and effective administration of the title IV-B and IV-E plans. The information collected is intended to be used for review and technical assistance processes.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

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

SUPPLEMENTARY INFORMATION:

Description: This initial request is to establish an overarching generic for CCWIS Review and Technical Assistance (TA) information collections and includes six initial TA tools for title

IV-E agencies to self-assess their conformity to CCWIS project and design requirements at 45 CFR 1355.52-3. The initial six TA tools include intake, investigation, case management, adoption, foster care and service provider management, and administration.

In the future, ACF will submit under this generic clearance mechanism additional TA tools for title IV-E agencies to self-assess design, data quality, usability, reporting, data exchanges, external systems, eligibility, finance, Child Welfare Contributing Agencies, and other tools, as needed, to assess new child welfare programs and modern system architecture.

The CCWIS requirements at 45 CFR 1355.55 require the review, assessment, and inspection of the planning, design, development, installation, operation, and maintenance of each CCWIS project on a continuing basis. The Advance Planning Document regulations at 45 CFR 95.621 require periodic reviews of state and local agency methods and practices to insure that information systems, including CCWIS, are utilized for purposes consistent with proper and efficient administration.

Respondents: Title IV-E agencies under the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
CCWIS Self-Assessment—Intake	55	1	10	550
CCWIS Self-Assessment—Investigation	55	1	10	550
CCWIS Self-Assessment—Case Management	55	1	10	550
CCWIS Self-Assessment—Adoption	55	1	10	550
CCWIS Self-Assessment—Foster Care and Service Provider Management	55	1	10	550
CCWIS Self-Assessment—Administration	55	1	10	550
Future Tools to be developed	55	10	12	6,600

Estimated Total Annual Burden Hours: 9,900.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

(Authority: 5 U.S.C. 301; 42 U.S.C. 470, 620 *et seq.*, 622(b), 629b(a), 652(b), 654A, 670 *et seq.*, 671(a), 1302, and 1396a(a))

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1301]

Q3C(R8) Recommendations for the Permitted Daily Exposures for Three Solvents—2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether, and Tert-Butyl Alcohol—According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Council for Harmonisation; Draft Guidance for Industry; Availability

Correction

In notice document 2020–11280, appearing on pages 31785 through 31786 in the issue of Wednesday, May 27, 2020 make the following correction.

On page 31785, in the first column, on the last line, “July 26, 2024” should read “July 27, 2020”.

[FR Doc. C1–2020–11280 Filed 6–4–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1335]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance and reissuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the coronavirus disease 2019 (COVID–19) public health emergency. FDA has issued, and in some cases reissued, the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by Secretary of Health and Human Services (HHS) that there is a public health emergency that has significant potential to affect national security or the health and security of U.S. citizens living abroad, which involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance and reissuance, are listed in this document and are available on FDA's website at the links indicated in this document.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION**

section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT:

Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;¹ (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency,

¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.