

- Information on the prevention materials developed and disseminated by the NRS.

- Information and analysis of the latest trends and their impact on runaway prevention.

The NRS will use two forms, one form to collect relevant information disclosed during calls, emails, and forum posts and a second form to collect information from chats. All data will be provided to

FYSB in the aggregate and no personally identifiable data are collected.

The information collected will allow FYSB to better understand the types of services needed by youth contacting the NRS, as well as to identify outreach and prevention strategies to increase the visibility of the NRS services among youth experiencing housing instability, homelessness, youth who run away, and youth in crisis. Additionally, the

findings from this data collection will be included in a required Report to Congress to provide relevant and up-to-date information on the status of youth in crisis and runaway and homeless youth nationwide.

Respondents: Youth and adults who contact the National Runaway Safeline during calls, chats, emails, and forum posts.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|----------------------------|-----------------------------|--|-----------------------------------|--------------------|---------------------|
| Youth in Crisis Form | 47,175 | 1 | .23 | 10,850 | 3,617 |
| NRS Live Chat Form | 29,679 | 1 | .65 | 19,291 | 6,430 |

Estimated Total Annual Burden Hours: 10,047.

Authority: Section 331 of the Runaway and Homeless Youth Act authorizes the award of grants for the National Communication System for Runaway and Homeless Youth (34 U.S.C. 11231).

John M. Sweet, Jr.,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Office of Refugee Resettlement Unaccompanied Refugee Minors Program Application and Withdrawal of Application or Declination of Placement Form (OMB #0970-0550)

AGENCY: Office of Refugee Resettlement, Administration for Children and

Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR) is requesting a three-year extension with revisions of the Unaccompanied Refugee Minors (URM) Program Application and Withdrawal of Application or Declination of Placement Form (OMB #0970-0550, expiration 08/31/2023). Proposed revisions include additional instructions, a small number of new questions, dropping a few questions, and rephrasing existing questions.

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

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The URM Program Application is completed on behalf of unaccompanied children in the United States who are applying for entry into the URM Program. The application includes biographical data and information on the child's needs to support placement efforts. The Withdrawal of Application or Declination of Placement Form is completed when a child is no longer interested in entering the URM Program or is not interested in entering the placement they were offered.

Respondents: Case managers, attorneys, or other representatives working with unaccompanied children who are eligible for the URM Program.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|--|-----------------------------|--|-----------------------------------|--------------------|---------------------|
| Unaccompanied Refugee Minors Program Application | 450 | 3 | 1.5 | 2,025 | 675 |
| Withdrawal of Application or Declination of Placement Form | 50 | 3 | 0.2 | 30 | 10 |

Estimated Total Annual Burden Hours: 685.

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: 8 U.S.C. 1522(d).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-3351]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Cepheid. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of February 10, 2023.

ADDRESSES: Submit written requests for a single copy of the EUA 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 Authorization.

FOR FURTHER INFORMATION CONTACT:

Jennifer 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 public health protections against biological, chemical, nuclear, and radiological 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 biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

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 (A) a biological, chemical, radiological, or nuclear agent or agents or (B) 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, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable

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.