Estimated Total Annual Burden Hours: 751,461.

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: 42 U.S.C. 666(a)(1), (a)(8), and (b)(6).

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–01130 Filed 1–20–23; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Budget and Narrative Justification Template (OMB #: 0970–0548)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to renew the collection of expenditure estimate forms for the tribal child support enforcement program through an optional financial reporting form, Tribal Budget and Narrative Justification Template (Office of Management and Budget (OMB) #: 0970–0548; expiration date June 30, 2023). No changes are proposed.

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: To receive child support funding under 45 CFR part 309, tribes and tribal organizations must submit the financial forms described in 45 CFR 309.130(b) and other forms as the Secretary may designate, due no later than August 1 annually. This optional template is designed for tribes operating an approved tribal child support enforcement program to use in preparing their annual budget and narrative justification estimates in accordance with the tribal child support enforcement regulations. The optional Tribal Budget and Narrative Justification Template helps improve efficiency and establish uniformity and consistency in the annual budget submission and review process. Tribes may use the Excel or Word version of the template to submit the required financial information.

Respondents: Tribes and Tribal Organizations administering a tribal child support program under title IV–D of 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	Annual burden hours
Tribal Budget and Narrative Justification—Excel	52	3	16	2,496	832
Tribal Budget and Narrative Justification—Word	8	3	20	480	160

Estimated Total Annual Burden Hours: 992.

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: 45 CFR 309.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–01129 Filed 1–20–23; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

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 or Agency) is announcing the issuance 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 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 the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that 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, are listed in this document, and can be accessed on FDA's website from the links indicated.

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

ADDRESSES: Submit written requests for single copies of an 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 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 of the 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 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 section 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 circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from *https://www.fda.gov/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.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from June 16, 2022, through December 6, 2022, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Genabio Diagnostics Inc.'s Genabio COVID–19 Rapid Self-Test Kit, issued July 8, 2022;
- Watmind USA's Speedy Swab Rapid COVID–19 Antigen Self-Test, issued July 8, 2022;
- Predicine, Inc.'s Predicine SARS–CoV–2 RT–PCR Test, issued July 19, 2022;
- Aptitude Medical Systems Inc.'s Metrix COVID–19 Test, issued October 18, 2022;
- Nanobiosym Precision Testing Services's The Nano Test for COVID–19, issued November 8, 2022;
- ANP Technologies, Inc.'s NIDS COVID–19 Antigen Home Test, issued November 17, 2022;
- Beijing Hotgen Biotech Co., Ltd.'s Hotgen COVID–19 Antigen Home Test, issued November 17, 2022;
- Premier Medical Laboratory Services's Diversified Medical Healthcare SARS–CoV–2 Assay, issued November 18, 2022;
- CorDx, Inc.'s CorDx COVID–19 Ag Test, issued November 21, 2022;
- Azure Biotech Inc.'s Fastep COVID–19 Antigen Home Test, issued November 21, 2022;
- ACON Laboratories, Inc.'s Flow*flex* COVID–19 Antigen Rapid Test, issued December 6, 2022.

FDA is hereby announcing the following Authorization for a multianalyte test:

- Lucira Health, Inc.'s Lucira COVID–19 and Flu Test, issued November 22, 2022.[4]

FDA is hereby announcing the following Authorization for a serology test:

- Diazyme Laboratories, Inc.'s Diazyme SARS–CoV–2 Neutralizing Antibody CLIA Kit, issued December 6, 2022.[5]

In addition, on November 1, 2022, FDA issued a letter to Developers of Antigen In Vitro Diagnostics (IVDs) Authorized for Emergency Use for Coronavirus Disease 2019 (COVID–19) as of Today's Date (November 1, 2022) for Revisions Related to Serial (Repeat) Testing for the EUAs of Antigen IVDs.[6]

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01180 Filed 1–20–23; 8:45 am]

BILLING CODE 4164–01–P

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus RNA, and that the known and potential benefits of the product, when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[5] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing recent or prior infection with SARS–CoV–2 by identifying individuals with an adaptive immune response to the virus that causes COVID–19, and that the known and potential benefits of the product, when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] FDA concluded revisions to the EUAs of the tests that are within the scope of the November 1, 2022, letter is appropriate to protect the public health or safety and revised all such EUAs pursuant to section 564(g)(2)(C) of the FD&C Act, including to revise the authorized use and to establish the additional condition set forth in the letter, as permitted by section 564(e) of the FD&C Act. The action is based on the available scientific evidence on the impact of serial testing on the performance of SARS–CoV–2 antigen tests. (Refer to: ''Performance of Screening for SARS–CoV–2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS–CoV–2 Infection: findings from the Test Us at Home prospective cohort study'' at *https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1.*) The letter revised all current EUAs for antigen SARS–CoV–2 IVD devices as of November 1, 2022, by: (1) revising the authorized use to be for serial testing at least twice over 3 days for individuals with symptoms of COVID–19 and, for tests previously authorized for testing individuals without symptoms, revising the authorized use to be for serial testing at least thrice over 5 days for individuals without symptoms of COVID–19, (2) establishing a new condition of authorization regarding updating authorized labeling, and (3) eliminating a condition of authorization regarding evaluating clinical performance to support the serial screening claim.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0945–0003]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 22, 2023.

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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0945–0003–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of