selected because of concerns about being able to recruit a sufficient number of participants for this particular study if we selected a cancer-specific sample.

We will ask consumers to consider a hypothetical scenario in which they have recently been diagnosed with cancer and are actively looking for available treatments. HCPs will be asked to consider a scenario in which they are actively looking for available treatments for a patient who has been diagnosed with cancer. We will also ask consumers if they have ever been diagnosed with cancer. HCP participants will be drawn from online HCP panels and general population consumer participants will be drawn from online consumer panels. Informed by power analyses, we will recruit a sample of 540 HCPs and 540 consumers for the main study.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents [2]	Number of responses per respondent	Total annual responses	Average burden per response [3]	Total hours
Pretest					
General population: Pretest screener completes (assumes 75% eligible)	528	1	528	0.08 (5 minutes)	42.2
General population: Number of completes, pretest	396	1	396	0.33 (20 minutes)	130.7
HCP: Pretest screener completes (assumes 60% eligible)	660	1	660	0.08 (5 minutes)	52.8
HCP: Number of completes, pretest	396	1	396	0.33 (20 minutes)	130.7
Main Study					
General population: Number of main study screener completes (assumes 75% eligible)	792	1	792	0.08 (5 minutes)	63.4
General population: Number of completes, main study	594	1	594	0.33 (20 minutes)	196.0
HCP: Number of main study screener completes (assumes 60% eligible)	990	1	990	0.08 (5 minutes)	79.2
HCP: Number of completes, main study	594	1	594	0.33 (20 minutes)	196.0
Total					891

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.
[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23507 Filed 10–27–21; 8:45 am]

BILLING CODE 4164–01–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) 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 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 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-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 1, 2021, through September 10, 2021, 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

[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.

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]

- OraSure Technologies, Inc.'s InteliSwab COVID–19 Rapid Test Pro, issued June 4, 2021;
- OraSure Technologies, Inc's InteliSwab COVID–19 Rapid Test, issued June 4, 2021;
- OraSure Technologies, Inc's InteliSwab COVID–19 Rapid Test Rx, issued June 4, 2021;
- Roche Molecular Systems' cobas SARS–CoV–2 Nucleic acid test for use on the cobas LIAT System (cobas SARS–CoV–2), issued June 17, 2021;
- WREN Laboratories LLC's WREN Laboratories COVID–19 PCR Test DTC, issued June 17, 2021;
- BioGX, Inc.'s BioGX *Xfree* COVID–19 Direct RT–PCR, issued June 29, 2021;
- Ellume Limited's Ellume.lab COVID Antigen Test, issued July 8, 2021;
- Thermo Fisher Scientific Inc's TaqPath COVID–19 RNase P Combo Kit 2.0, issued July 8, 2021;
- GenBody Inc.'s GenBody COVID–19 Ag, issued July 13, 2021;
- PHASE Scientific International, Ltd.'s INDICAID COVID–19 Rapid Antigen Test, issued July 28, 2021;
- Life Technologies Corporation's (a part of Thermo Fisher Scientific, Inc.) TaqPath COVID–19 Fast PCR Combo Kit 2.0, issued July 30, 2021;
- Access Bio, Inc.'s *CareStart* COVID–19 Antigen Home Test, issued August 2, 2021;
- Life Technologies Corporation's (a part of Thermo Fisher Scientific, Inc.) TaqPath COVID–19 MS2 Combo Kit 2.0, issued August 2, 2021;
- QIAGEN GmbH's QIAreach SARS–CoV–2 Antigen Test, issued August 5, 2021;
- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's SelfCheck COVID–19 TaqPath Multiplex PCR, issued August 9, 2021;
- STS Lab Holdco's Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR DTC Test (''Amazon Multi-Target DTC Test''), issued August 11, 2021;
- STS Lab Holdco's Amazon Multi-Target SARS–CoV–2 Real-Time RT–PCR Test (''Amazon Multi-Target Test''), issued August 11, 2021;
- The Mount Sinai Hospital, Center for Clinical Laboratories' Mount Sinai SARS–CoV–2 Assay, issued August 23, 2021;
- Becton, Dickinson and Company's BD Veritor At-Home COVID–19 Test, issued August 24, 2021;
- Empire City Laboratories' ECL COVID TEST SYSTEM, issued August 25, 2021;
- Empire City Laboratories' ECL COVID TEST SYSTEM–1, issued August 25, 2021; and
- Yale School of Public Health, Department of Epidemiology of Microbial Diseases' SalivaDirect for use with DTC Kits, issued August 27, 2021.

FDA is hereby announcing the following Authorizations for serology tests: [4]

- Diabetomics, Inc.'s CovAb SARS–CoV–2 Ab Test, issued June 4, 2021;
- Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARS–CoV–2 IgG (sCOVG), issued June 17, 2021;
- Access Bio, Inc.'s *CareStart* EZ COVID–19 IgM/IgG, issued June 24, 2021;
- Bio-Rad Laboratories' BioPlex 2200 SARS–CoV–2 IgG, issued July 1, 2021;
- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 IgG Quantitative Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti- SARS–CoV–2 IgG Quantitative Calibrator, issued July 9, 2021; [5]
- Ortho-Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products Anti-SARS–CoV–2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS–CoV–2 Total N Antibody Calibrators, issued July 22, 2021; [6]
- LumiraDx UK Ltd.'s LumiraDx SARS–CoV–2 Ab Test, issued August 2, 2021; and
- InBios International, Inc.'s SCoV–2 *Detect* IgG Rapid Test, issued August 24, 2021.

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics:

- Exact Sciences Laboratories' COVID–Flu Multiplex Assay, issued July 1, 2021 [7] and
- Cepheid's Xpert Xpress CoV–2/Flu/RSV *plus,* issued September 10, 2021.[8]

FDA is hereby announcing the following Authorizations for other medical devices:

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 EUAs for these products, unless otherwise noted in this document, 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 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 products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[5] As set forth in this EUA, 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 aiding in 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] As set forth in this EUA, 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 aiding in 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.

[7] As set forth in the EUA, 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 COVID–Flu Multiplex Assay may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus nucleic acids and that the known and potential benefits of the COVID–Flu Multiplex Assay when used for diagnosing COVID–19, outweigh the known and potential risks of the COVID–Flu Multiplex Assay; and (3) there is no adequate, approved, and available alternative to the emergency use of the COVID–Flu Multiplex Assay.

[8] As set forth in the EUA, 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 Xpert Xpress CoV–2/Flu/RSV *plus* may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of nucleic acid from SARS–CoV–2 virus, influenza A, influenza B and respiratory syncytial virus (RSV) and that the known and potential benefits of the Xpert Xpress CoV–2/Flu/RSV *plus* when used for diagnosing COVID–19, outweigh the known and potential risks of the Xpert Xpress CoV–2/Flu/RSV *plus;* and (3) there is no adequate, approved, and available alternative to the emergency use of the Xpert Xpress CoV–2/Flu/RSV *plus.*

- WREN Laboratories LLC's WREN Laboratories COVID–19 Saliva Test Collection Kit DTC, issued June 17, 2021; [9]
- Tidal Medical Technologies LLC's InSee incentive spirometer accessory, issued June 30, 2021; [10]
- Everlywell, Inc.'s Everlywell COVID–19 & Flu Test Home Collection Kit, issued July 1, 2021; [11]
- Becton, Dickinson and Company's BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), issued July 22, 2021; [12]
- Kwokman Diagnostics, LLC's Kwokman Diagnostics COVID–19 Home Collection Kit, issued August 13, 2021; [13] and
- Yale School of Public Health, Department of Epidemiology of Microbial Diseases' SalivaDirect DTC Saliva Collection Kit, issued August 27, 2021.[14]

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23501 Filed 10–27–21; 8:45 am]

BILLING CODE 4164–01–P

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 WREN Laboratories COVID–19 Saliva Test Collection Kit DTC may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC when used for such use, outweigh the known and potential risks of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 InSee COVID–19 may be effective in treating respiratory conditions in patients with COVID–19 in hospital settings by quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer, and that the known and potential benefits of the InSee when used for treating COVID–19, outweigh the known and potential risks of InSee; and (3) there is no adequate, approved, and available alternative to the emergency use of the InSee for treating COVID–19 for such use.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 Everlywell COVID–19 & Flu Test Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 influenza A and/or influenza B nucleic acids from the home collected human specimen and that the known and potential benefits of the Everlywell COVID–19 & Flu Test Home Collection Kit when used for diagnosing COVID–19, outweigh the known and potential risks of the Everlywell COVID–19 & Flu Test Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the Everlywell COVID–19 & Flu Test Home Collection Kit.

[12] FDA is using the term ''UK Manufacturing Site'' to differentiate the authorized version from the FDA-cleared version of these products that are also manufactured by Becton, Dickinson and Company. As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) may be effective in aiding in the identification and treatment of coagulopathy in patients, including patients with known or suspected COVID–19, by collecting, transporting, and storing blood specimens for coagulation testing, and that the known and potential benefits of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) when used for such use, outweigh the known and potential risks of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site); and (3) there is no adequate, approved, and available alternative to the emergency use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site).

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 Kwokman Diagnostics COVID–19 Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the Kwokman Diagnostics COVID–19 Home Collection Kit when used for such use, outweigh the known and potential risks of the Kwokman Diagnostics COVID–19 Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the Kwokman Diagnostics COVID–19 Home Collection Kit.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, 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 SalivaDirect DTC Saliva Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the SalivaDirect DTC Saliva Collection Kit when used for such use, outweigh the known and potential risks of the SalivaDirect DTC Saliva Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the SalivaDirect DTC Saliva Collection Kit.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updated HRSA-Supported Women's Preventive Services Guidelines: Contraception and Screening for HIV Infection

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice seeks comments on two updated draft recommendations for (1) providing contraception and (2) screening for human immunodeficiency virus (HIV) infection, as part of the HRSA-supported Women's Preventive Services Guidelines (Guidelines). These updated draft recommendations have been developed through a national cooperative agreement, the Women's Preventive Services Initiative (WPSI), by the American College of Obstetricians and Gynecologists (ACOG). Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury have previously issued regulations, which describe how group health plans and health insurance issuers apply the coverage requirements, including the use of reasonable medical management. (*See* 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130).

DATES: Members of the public are invited to provide written comments no later than November 29, 2021. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee.

ADDRESSES: Members of the public interested in providing comments on the draft recommendation statements can do so by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: As provided for in section 1001(5) of the