records, *e.g.,* the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records.

Dated: April 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08480 Filed 4–22–21; 8:45 am]

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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 are available on FDA's website at 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 (CDC) (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.

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 at *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, are available on the internet 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 September 15, 2020, through February 15, 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 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 multi-analyte tests: [3]

- Visby Medical, Inc.'s Visby Medical COVID–19, issued September 16, 2020;
- GK Pharmaceuticals Contract Manufacturing Operations' GK ACCU–RIGHT SARS–CoV–2 RT–PCR KIT, issued September 18, 2020;
- KimForest Enterprise Co., Ltd.'s KimForest SARS–CoV–2 Detection Kit v1, issued September 21, 2020;
- Vela Operations Singapore Pte. Ltd.'s ViroKey SARS–CoV–2 RT–PCR Test v2.0, issued September 22, 2020;
- Quadrant Biosciences Inc.'s Clarifi COVID–19 Test Kit, issued September 22, 2020;
- Clear Labs, Inc.'s Clear Dx SARS–CoV–2 Test, issued September 23, 2020;
- Genetrack Biolabs, Inc.'s Genetrack SARS–CoV–2 Molecular Assay, issued September 25, 2020;
- National Jewish Health's SARS–CoV–2 MassArray Test, issued September 29, 2020;
- Akron Children's Hospital's Akron Children's Hospital SARS–CoV–2 Assay, issued September 29, 2020;
- CENTOGENE US, LLC's CentoSure SARS–CoV–2 RT–PCR Assay, issued September 29, 2020;
- Aeon Global Health's Aeon Global Health SARS–CoV–2 Assay, issued September 30, 2020;
- Alimetrix, Inc.'s Alimetrix SARS–CoV–2 RT–PCR Assay, issued September 30, 2020;
- Tempus Labs, Inc.'s iC SARS–CoV2 Test, issued October 1, 2020;
- UMass Memorial Medical Center's UMass Molecular Virology Laboratory 2019–nCoV rRT–PCR Dx Panel, issued October 1, 2020;
- SEASUN BIOMATERIALS, Inc.'s AQ–TOP COVID–19 Rapid Detection Kit PLUS, issued October 5, 2020;
- University of California, Los Angeles's (UCLA's) UCLA SwabSeq COVID–19 Diagnostic Platform, issued October 6, 2020;
- Access Bio, Inc.'s CareStart COVID–19 Antigen, issued October 8, 2020;
- LumiraDx UK Ltd.'s LumiraDx SARS–CoV–2 RNA STAR Complete, issued October 14, 2020;
- Celltrion USA, Inc.'s Sampinute COVID–19 Antigen MIA, issued October 23, 2020;
- Agena Bioscience, Inc.'s MassARRAY SARS–CoV–2 Panel, issued October 26, 2020;
- Lucira Health, Inc.'s Lucira COVID–19 All-In-One Test Kit, issued November 17, 2020;
- Gravity Diagnostics, LLC's Gravity Diagnostics SARS–CoV–2 RT–PCR Assay, issued November 23, 2020;
- Cepheid's Xpert Omni SARS–CoV–2, issued November 27, 202;
- Luminostics, Inc.'s Clip COVID Rapid Antigen Test, issued December 7, 2020;
- Laboratory Corporation of America's Pixel by LabCorp COVID–19 Test Home Collection Kit, issued December 9, 2020;
- ResearchDx, Inc., DBA Pacific Diagnostics' PacificDx Covid–19 Test, issued December 11, 2020;
- RCA Laboratory Services LLC dba GENETWORx's GENETWORx Covid–19 Nasal Swab Test, issued December 15, 2020;
- Ellume Limited's Ellume COVID–19 Home Test, issued December 15, 2020;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID–19 Ag Card Home Test, issued December 16, 2020;
- Materials and Machines Corporation of America's (DBA MatmaCorp, Inc.) MatMaCorp COVID–19 2SF Test, issued December 17, 2020;
- Quidel Corporation's QuickVue SARS Antigen Test, issued December 18, 2020;
- Quidel Corporation's Solana SARS–CoV–2 Assay, issued December 23, 2020;
- Cepheid's Xpert Xpress SARS–CoV–2 DoD, issued December 23, 2020;
- Quanterix Corporation's Simoa SARS–CoV–2 N Protein Antigen Test, issued January 5, 2021;

[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.

[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.

• Ortho Clinical Diagnostics, Inc.'s VITROS Immunodiagnostic Products SARS–CoV–2 Antigen Reagent Pack used in combination with the VITROS Immunodiagnostic Products SARS–CoV–2 Antigen Calibrator, issued January 11, 2021;
• SML GENETREE Co., Ltd.'s Ezplex SARS–CoV–2 G Kit, issued January 13, 2021;
• Bio-Rad Laboratories, Inc.'s Bio-Rad Reliance SARS–CoV–2 RT–PCR Assay Kit, issued January 15, 2021;
• Ambry Genetics Laboratory's Ambry COVID–19 RT–PCR Test, issued January 22, 2021;
• Clinomics USA Inc.'s Clinomics TrioDx RT–PCR COVID–19 Test, issued February 4, 2021;
• Visby Medical, Inc.'s Visby Medical COVID–19 Point of Care Test, issued February 8, 2021;
• Grifols Diagnostic Solutions Inc.'s Procleix SARS–CoV–2 Assay, issued February 10, 2021;
• Assurance Scientific Laboratories' Assurance SARS–CoV–2 Panel DTC, issued February 13, 2021; and
• Gravity Diagnostics, LLC's Gravity Diagnostics SARS–CoV–2 RT–PCR for use with DTC kits, issued February 13, 2021.

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

• Jiangsu Well Biotech Co., Ltd.'s Orawell IgM/IgG Rapid Test, issued September 23, 2020;
• Quotient Suisse SA's MosaiQ COVID–19 Antibody Magazine, issued September 25, 2020;
• Nirmidas Biotech, Inc.'s Nirmidas COVID–19 (SARS–CoV–2) IgM/IgG Antibody Detection Kit, issued September 29, 2020;
• NanoEntek America, Inc.'s FREND COVID–19 total Ab, issued September 29, 2020;
• DiaSorin, Inc.'s DiaSorin LIAISON SARS–CoV–2 IgM Assay, issued September 29, 2020;
• Thermo Fisher Scientific's OmniPATH COVID–19 Total Antibody ELISA Test, issued October 2, 2020;
• ZEUS Scientific, Inc.'s ZEUS ELISA SARS–CoV–2 IgG Test System Company, issued October 6, 2020;
• Genalyte, Inc.'s Maverick SARS–CoV–2 Multi-Antigen Serology Panel v2, issued October 8, 2020;
• Beckman Coulter, Inc.'s Access SARS–CoV–2 IgM, issued October 8, 2020;
• Abbott Laboratories Inc.'s AdviseDx SARS–CoV–2 IgM, issued October 9, 2020;
• Quansys Biosciences, Inc.'s Q-Plex SARS–CoV–2 Human IgG (4 Plex), issued October 28, 2020;
• GenScript USA Inc.'s cPass SARS–CoV–2 Neutralization Antibody Detection Kit, issued November 6, 2020;
• Innovita (Tangshan) Biological Technology Co., Ltd.'s Innovita 2019–nCoV Ab Test (Colloidal Gold), issued November 23, 2020;
• Kantaro Biosciences, LLC's COVID–SeroKlir, Kantaro Semi-Quantitative SARS–CoV–2 IgG Antibody Kit, issued November 24, 2020;
• Roche Diagnostics, Inc.'s Elecsys Anti-SARS–CoV–2 S, issued November 25, 2020;
• ACON Laboratories, Inc.'s ACON SARS–CoV–2 IgG/IgM Rapid Test, issued December 15, 2020;
• Quanterix Corporation's Simoa Semi-Quantitative SARS–CoV–2 IgG Antibody Test, issued December 23, 2020;
• Nirmidas Biotech, Inc.'s MidaSpot COVID–19 Antibody Combo Detection Kit, issued December 31, 2020;
• Siemens Healthcare Diagnostics Inc.'s Dimension Vista SARS–CoV–2 IgG (COV2G), issued January 8, 2021;
• Siemens Healthcare Diagnostics Inc.'s Dimension EXL SARS–CoV–2 IgG (CV2G), issued January 8, 2021;
• ADVAITE, Inc.'s RapCov Rapid COVID–19 Test, issued January 11, 2021;
• Phadia AB's EliA SARS–CoV–2–Sp1 IgG Test, issued January 11, 2021;
• United Biomedical, Inc.'s UBI SARS–CoV–2 ELISA, issued January 15, 2021; and
• Immunodiagnostic Systems Ltd's IDS SARS–CoV–2 IgG, issued February 10, 2021.

FDA is hereby announcing the following Authorizations for multi-analyte in vitro diagnostics: [5]

• Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV, issued September 24, 2020;
• BioFire Diagnostics, LLC's BioFire Respiratory Panel 2.1–EZ (RP2.1–EZ), issued October 2, 2020;
• Quidel Corporation's Sofia 2 Flu + SARS Antigen FIA, issued October 2, 2020;
• GenMark Diagnostics, Inc.'s ePlex Respiratory Pathogen Panel 2 (ePlex RP2 Panel), issued October 7, 2020;
• Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics RC COVID–19 +Flu RT–PCR, issued December 4, 2020;
• Hologic, Inc.'s Aptima SARS–CoV–2/Flu assay, issued December 16, 2020;
• Princeton BioMeditech Corp.'s Status COVID–19/Flu, issued February 4, 2021;
• Becton, Dickinson and Company's BD SARS–CoV–2/Flu for BD MAX System, issued February 10, 2021;
• Thermo Fisher Scientific's TaqPath COVID–19, FluA, FluB Combo Kit, issued February 10, 2021; and
• Bio-Rad Laboratories, Inc.'s Bio-Rad Reliance SARS–CoV–2/FluA/FluB RT–PCR Assay Kit, issued February 11, 2021.

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

• Duke University's COVIAGE, issued September 24, 2020; [6]
• Dascena, Inc.'s COViage Hemodynamic Instability and Respiratory Decompensation Prediction System (COViage), issued September 24, 2020; [7]

[4] 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 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 the EUAs, 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 (through the simultaneous detection and differentiation of SARS–CoV–2 and various other pathogens (see individual EUAs for specific other pathogens)) and that the known and potential benefits of the products when used for such a 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.

[6] 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 COVIAGE may be effective in preventing healthcare providers' exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of COVIAGE for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of COVIAGE.

[7] 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 COViage may be effective when used by healthcare providers as a diagnostic aid to assist with the early identification of adult COVID–19 patients (18 years

Continued

• Beckman Coulter, Inc's Access IL–6, issued October 1, 2020; [8]

• Spectrum Solutions LLC's SDNA–1000 Saliva Collection Device, issued October 8, 2020; [9]

• Roxby Development, LLC's Zoe-Ann Decontamination System, issued October 20, 2020; [10]

• DNA Genotek Inc.'s OMNIgene·ORAL OM–505 and OME–505 (OMNIgene·ORAL) saliva collection devices, issued October 14, 2020; [11]

• Clinical Enterprise, Inc.'s EmpowerDX At-Home COVID–19 PCR Test Kit, issued on October 15, 2020; [12]

• binx health, Inc.'s binx health At-Home Nasal Swab COVID–19 Sample Collection Kit, issued October 20, 2020; [13]

• DNA Genotek Inc.'s ORAcollect•RNA OR–100 and ORAcollect•RNA ORE–100 saliva collection devices, issued October 28, 2020; [14]

• Terumo Cardiovascular's CAPIOX Emergency Bypass System (CAPIOX EBS), issued November 21, 2020; [15]

• RapidRona, Inc.'s RapidRona Self-Collection Kit, issued November 23, 2020; [16]

• 3B Medical, Inc.'s Lumin LM3000 Bioburden Reduction UV System (''Lumin LM3000''), issued December 3, 2020; [17]

• Ecolab Inc.'s Bioquell Technology System, issued December 4, 2020; [18]

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of age or older who are admitted to the hospital) who are likely to be diagnosed with hemodynamic instability or respiratory decompensation, which are common complications associated with COVID–19, and that the known and potential benefits of COViage, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of COViage when used by healthcare providers as a diagnostic aid to assist with the early identification of adult COVID–19 patients who are likely to be diagnosed with hemodynamic instability or respiratory decompensation, which are common complications associated with COVID–19.

[8] 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 product may be effective in treating COVID–19, by assisting in identifying severe inflammatory response in patients with confirmed COVID–19 illness to aid in determining the risk of intubation with mechanical ventilation, 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.

[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 product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect, stabilize, and maintain during transport, unprocessed saliva specimens suspected of containing SARS–CoV–2 RNA, and that the known and potential benefits of the products 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.

[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 Zoe-Ann Decontamination System may be effective at decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Zoe-Ann Decontamination System for decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[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 product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS–CoV–2 RNA, 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.

[12] 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 product 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 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.

[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 product may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human nasal swab specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected specimen, and that the known and potential benefits of the product when used for diagnosing COVID–19, 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.

[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 product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS–CoV–2 RNA, 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.

[15] 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 CAPIOX EBS may be effective in treating COVID–19 by providing long-term (≤ 6 hours) respiratory or cardiopulmonary support to treat patients 18 years or older with COVID–19 who have acute respiratory failure or acute cardiopulmonary failure where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent, and that the known and potential benefits of the CAPIOX EBS for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the CAPIOX EBS when there are shortages of FDA-cleared alternatives during the COVID–19 pandemic.

[16] 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 product may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human nasal swab specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected specimen, and that the known and potential benefits of the product when used for diagnosing COVID–19, 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.

[17] 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 Lumin LM3000 may be effective at bioburden reduction of compatible N95 respirators for single-user reuse by healthcare providers to supplement CDC reuse recommendations to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Lumin LM3000 for bioburden reduction of compatible N95 respirators for single-user reuse by healthcare providers to supplement CDC reuse recommendations to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[18] 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

• SCONE Medical Solutions Inc.'s SCONE, issued December 18, 2020; [19]

• Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur IL6 assay, issued December 18, 2020; [20]

• Yale New Haven Health System's Yale New Haven Health FILTERING FACEPIECE RESPIRATOR Decontamination System, issued January 15, 2021; [21] and

• Everlywell, Inc.'s Everlywell COVID–19 Test Home Collection Kit DTC, issued February 13, 2021.[22]

Dated: April 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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FDA, it is reasonable to believe that the Bioquell Technology System may be effective at decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Bioquell Technology System for decontaminating compatible N95 respirators for single-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[19] 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 SCONE may be effective in preventing healthcare providers exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport for a maximum duration of use of 30 minutes, of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of SCONE for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of SCONE.

[20] 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 product may be effective in treating COVID–19, by assisting in identifying severe inflammatory response in patients with confirmed COVID–19 illness to aid in determining the risk of intubation with mechanical ventilation, 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.

[21] 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 Yale New Haven Health filtering facepiece respirator decontamination system may be effective at decontaminating compatible N95 respirators for multiple-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the Yale New Haven Health filtering facepiece respirator Decontamination System for decontaminating compatible N95 respirators for multiple-user reuse by healthcare providers to prevent exposure to SARS–CoV–2 and other pathogenic biological airborne particulates during filtering facepiece respirator shortages during the COVID–19 pandemic.

[22] 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 product 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 product when used for diagnosing COVID–19, 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0001]

Model Informed Drug Development Approaches for Immunogenicity Assessments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research, in collaboration with the Center for Drug Evaluation and Research, is announcing the following public workshop entitled ''Model Informed Drug Development Approaches for Immunogenicity Assessments.'' The purpose of this public workshop is to discuss the best practices and future directions of quantitative methods for predicting immunogenicity of biological products. This public workshop is also being conducted to satisfy one of FDA's performance goals included in the sixth reauthorization of the Prescription Drug User Fee Amendments (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), to hold a series of workshops related to model-informed drug development (MIDD).

DATES: The public workshop will be held virtually on June 9, 2021, from 8 a.m. to 5 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all participants will be joining this public workshop via an online teleconferencing platform. The public workshop will be held virtually via Adobe Connect. Webcast information will be provided upon completion of registration.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, *CBERPublicEvents@fda.hhs.gov* (subject line: MIDD Workshop).

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, and in accordance with section I, part J of the PDUFA VI Performance Goals, FDA agreed to convene a series of workshops to identify best practices for MIDD (*https://www.fda.gov/media/99140/download,* see page 27). Each workshop focuses on current and emerging scientific approaches, including methodological limitations. The workshop announced in this notice fulfills FDA's performance commitment under PDUFA VI, specifically for modeling immunogenicity and correlates of protection for evaluating biological products, including vaccines and blood products.

II. Topics for Discussion at the Public Workshop

Topics for discussion include the following:

1. Current in silico methodologies used to assess drug immunogenicity;
2. Available data resources and data needs for MIDD approaches to evaluate immunogenicity at various stages of drug development;
3. Possible applications and limitations of MIDD approaches for desired immunogenicity of vaccine/allergenic products; and
4. Insight into the possible future applications of MIDD and good modeling practices.

A detailed agenda will be posted in advance of the workshop at *https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/workshops-meetings-conferences-biologics.*