is currently in commercial distribution in the United States.

- The establishment is willing to participate in an onsite or hybrid assessment.

B. Requests To Participate

Drug product manufacturers that are eligible and interested in participating in the voluntary QMM Prototype Assessment Protocol Evaluation Program should submit a request directly to Conchetta Newton (see **FOR FURTHER INFORMATION CONTACT**). To be considered for this program, a request should include all the following information: (1) a contact person (name and email); (2) manufacturing establishment address; (3) FDA Establishment Identifier and Data Universal Numbering System Numbers; (4) a brief description of the business operations (*e.g.,* manufacturing, testing, re/packaging, re/labeling, sterilizing, storing, distributing, or salvaging) conducted at the establishment; and (5) confirmation that the establishment features the characteristics discussed in section II.A of this notice.

C. Selection Process

FDA intends to select participants that reasonably reflect the diversity of the industry. FDA intends to notify each establishment of FDA's decision on their request to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program within 90 days of receipt. FDA intends to select up to nine volunteer participants for this program.

D. FDA-Participant Interactions

FDA intends to notify selected participants of their selection and confirm participation. This notification will include more information about engagement with the Agency, including an orientation and a pre-assessment questionnaire to assist the establishment in preparing for the assessment, logistical information such as options for dates and times to schedule the assessment, and recommendations for establishment personnel that should be available during the assessment. Teams of three assessors will conduct the prototype assessment protocol over a period that is expected to be up to five business days. Each team will be composed of CDER staff, or a combination of CDER staff and contractors. Following completion of the assessment, each participating establishment will receive a report summarizing areas of strength and growth opportunities. In addition, approximately 6 months after the assessment, FDA will followup with a virtual meeting to get feedback on the prototype assessment protocol, the report, and any limitations encountered. This will help the Agency evaluate use of the protocol, including whether it enables meaningful assessment of the establishment's quality management practices and if feedback for the establishment is actionable.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement,'' 85 FR 65824, October 16, 2020, *https://www.federalregister.gov/d/2020-22976.*

* 2. ''Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement,'' 85 FR 65828, October 16, 2020, *https://www.federalregister.gov/d/2020-22977.*

3. J. Maguire, A. Fisher, D. Harouaka, N. Rakala, et al., 2023, ''Lessons from CDER's Quality Management Maturity Pilot Programs,'' *AAPS Journal,* 25(14), January 10, 2023, *https://doi.org/10.1208/s12248-022-00777-z.*

Dated: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01423 Filed 1–24–24; 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 or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to Coronavirus Disease 2019 (COVID–19). 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 Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, 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 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 Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (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 April 14, 2023, through December 8, 2023, 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

[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.

diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Azure Biotech, Inc.'s Azure Fatep COVID–19 Antigen Pen Home Test, issued April 14, 2023;
- MedArbor, LLC dba MedArbor Diagnostics' MedArbor Diagnostics SARS–CoV–2 Assay, issued April 19, 2023;
- Princeton BioMeditech Corp's Status COVID–19 Antigen Rapid Test for Home Use, issued April 24, 2023;
- University of Massachusetts' ICTC SARS–CoV–2 RT–PCR Assay, issued April 26, 2023;
- Drexel University College of Medicine's SARS–CoV–2 DUCoM–PDL Modified Tetracore Assay, issued on April 28, 2023;
- Access Medical Laboratories, Inc.'s Global Direct RT–PCR Test, issued on May 3, 2023;
- Nano-Ditech Corporation's Nano-Check COVID–19 Antigen At-Home Test, issued on May 12, 2023;
- BioTeke USA, LLC's Bio-Self COVID–19 Antigen Home Test, issued on May 22, 2023;
- Acutis Diagnostics' SARS–CoV–2 Acutis Multiplex Assay, issued on June 06, 2023;
- Michigan State University laboratories, Department of Medicine Olin Student Health Center's In-Dx SARS–CoV–2 RT–LAMP Assay, issued on June 08, 2023;
- Discover Labs' Discover Labs COVID–19 Assay, issued on June 30, 2023;
- Immunostics Inc.'s Swab-N-Go Home Test COVID–19 Ag, issued on July 17, 2023;
- Alphadera Labs, LLC's ALPHADx SARS–COV–2RT–PCR Test, issued on July 20, 2023;
- Laboratory Corporation of America's Clear Dx SARS–CoV–2 WGS v3.0 Test, issued on August 1, 2023; and
- 3EO Health, Inc.'s 3EO Health COVID–19 Test, issued on September 19, 2023.
- Tangen Biosciences, Inc.'s TangenDx SARS–CoV–2 Molecular Test, issued September 29, 2023;
- SD Biosensor, Inc.'s STANDARD Q COVID–19 Ag Test 2.0, issued September 29, 2023;
- MAWD Laboratories' MAWD Laboratories SARS–CoV–2 Dual Target by RT–PCR, issued on October 13, 2023;
- RCA Laboratory Services LLC dba GENETWORx's Gx HTIQ SARS–CoV–2 Test, issued December 08, 2023; and
- RCA Laboratory Services LLC dba GENETWORx's Gx HTKB SARS–CoV–2 Test, issued on December 08, 2023.

FDA is hereby announcing the following Authorizations for multianalyte tests:

- Princeton BioMeditech Corp's ViraDx SARS–CoV–2/Flu A+B Rapid Antigen Test, issued on September 8, 2023.[4]
- Roche Molecular Systems's cobas SARS–CoV–2 & Influenza A/B v2, issued on November 16, 2023.[5]

Dated: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01426 Filed 1–24–24; 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 detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus nucleocapsid protein antigens, 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 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–0449]

Determination of Regulatory Review Period for Purposes of Patent Extension; CABENUVA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for CABENUVA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by March 25, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 23, 2024. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the