fiscal and administrative management of early childhood programs and grants?

- Given existing challenges with recruiting, hiring, and retaining qualified tribal early childhood program staff, what TA would be helpful to support tribal communities in building, supporting, strengthening, and maintaining an effective early childhood workforce?
- What TA would be helpful to support tribal communities in planning for, developing, building, maintaining, and improving appropriate early care and education facilities?
- What TA supports do tribal communities need or want around data collection and management, data systems, and data sovereignty in their early childhood programs and systems?
- What TA would be helpful to support tribal communities in implementing continuous quality improvement and evaluation initiatives in their early childhood programs and systems?
- What TA would be helpful to support tribal communities directly implementing high-quality early childhood programs and services (including evidence-based, developmentally appropriate practices, as well as infant and toddler programs and services to children with disabilities)?
- What TA would be helpful to support tribal early childhood programs in implementation of health, behavioral health, nutrition services, as appropriate?
- What TA would be helpful to support tribal early childhood programs and communities in effectively engaging families, elders, and community members and promoting family leadership (*i.e.,* empowering families to have a voice in program planning, implementation, and evaluation and advocate for their children)?
- What TA would be helpful to support tribal communities in developing, implementing, and overseeing (1) subsidy and certificate programs, (2) licensing programs, and (3) grants and contracts for early childhood services?
- What TA would be helpful to better support (1) tribal-level coordination and integration of early childhood programs and supports and (2) development of early childhood systems?
- What TA would be helpful to support tribes, when they desire, to collaborative effectively with states on implementation of early childhood programs and services?
- Are there any other key topic areas where TA would be helpful to support tribal communities in implementation and coordination of early childhood programs and systems? Are there any specific considerations around implementing possible new child care or preschool programs?

3.2 In your opinion, what is the ability and capacity of the current federal early childhood TA system to support tribal communities in the areas where TA is needed?

- What are the strengths of the existing TA system?
- Where are the gaps in the existing TA system?
- What existing resources could be more fully leveraged or tailored to be responsive to tribal early childhood programs and the needs of tribal communities?

3.3 In your opinion, what is the ideal structure of a TA network to provide support to tribal communities around implementation and coordination of early childhood programs and systems?

- What is the ideal overall organization of a federal tribal early childhood TA system (*e.g.,* national coordinating centers, regional-specific centers, topic-specific centers)?
- What are the best ways to ensure that federal TA is well-coordinated?
- What are the needed skills, background, capacities, experiences, and resources of entities and individuals providing TA to tribal communities implementing early childhood programs and systems?
- What are the best strategies for providing TA to tribal communities to implement coordinated early childhood programs and supports (*e.g.,* universal, targeted, intensive)?
- What are the ideal methods for providing TA to tribal communities on early childhood programs (*e.g.,* written resources, tools, webinars, trainings, meetings, site visits, peer learning and collaboration, coaching)?

3.4 If new or expanded TA supports are needed to support tribal early childhood program implementation and coordination, in your opinion, in what ways can the field (including TA providers) build capacity to provide the needed TA to tribal communities?

- Are there organizations or entities that are capable to serve as TA providers?
- Is there a pool of people who have the skills and experience necessary, including understanding the context of tribal communities, tribal sovereignty, culture and language, and tribal early childhood programs, to provide the TA that is needed?
- How can the TA system build capacity without negatively impacting tribal communities themselves (*e.g.,* by hiring away experienced staff)?
- How could potential new TA investments be integrated into the existing network of federal tribal early childhood TA providers?

3.5 In your opinion, do different types of tribal communities have different TA needs and priorities (topics, methods, strategies)?

- Larger tribal communities?
- Smaller tribal communities?
- Alaska Native communities?
- Urban Indian communities?
- Tribes that are consolidating child care into their 102–477 employment, training, and related services plans?

3.6 In your opinion, what are key challenges and lessons learned in providing effective TA to tribal communities to implement coordinated early childhood programs and systems?

- What are the primary challenges or barriers?
- For entities that have provided TA to tribal communities on these topics, what are some key lessons learned?

Authority: Section 511, Title V of the Social Security Act (42 U.S.C. 711); Head Start Act, as amended (42 U.S.C. 9801 et seq.); CCDB Act of 2014, as amended (Pub. L. 113–186).

Katie Hamm,

Deputy Assistant Secretary for Early Childhood Development Administration for Children and Families U.S. Department of Health and Human Services.

[FR Doc. 2022–05962 Filed 3–21–22; 8:45 am]

BILLING CODE 4184–74–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 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

[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.

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 September 11, 2021, through January 24, 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]

- Life Sciences Testing Center's Life Sciences Testing Center COVID–19 Test, issued September 22, 2021;
- ANP Technologies, Inc.'s NIDS COVID–19 Antigen Rapid Test Kit, issued September 24, 2021;
- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's SelfCheck cobas SARS–CoV–2 Assay, issued September 29, 2021;
- ACON Laboratories, Inc.'s Flow*flex* COVID–19 Antigen Home Test, issued October 4, 2021;
- Xtrava Health's SPERA COVID–19 Ag Test, issued October 12, 2021;
- LMSI, LLC's (d/b/a Lighthouse Lab Services) CovidNow SARS–CoV–2 Assay, issued October 14, 2021;
- Celltrion USA, Inc.'s Celltrion DiaTrust COVID–19 Ag Home Test, issued October 21, 2021;
- Detect, Inc's Detect Covid–19 Test, issued October 28, 2021;
- Talis Biomedical Corporation's Talis One COVID–19 Test System, issued November 5, 2021;
- iHealth Labs, Inc.'s iHealth COVID–19 Antigen Rapid Test, issued November 5, 2021;
- Meridian Bioscience, Inc.'s Revogene SARS–CoV–2, issued November 9, 2021;
- InBios International Inc.'s SCoV–2 Ag *Detect* Rapid Self-Test, issued November 22, 2021;
- Nano-Ditech Corp.'s Nano-Check COVID–19 Antigen Test, issued December 6, 2021;
- UCSD BCG EXCITE Lab's UCSD EXCITE COVID–19 Test, issued December 17, 2021;
- SD Biosensor, Inc.'s COVID–19 At-Home Test, issued December 24, 2021;
- Siemens Healthineers' CLINITEST Rapid COVID–19 Antigen Self-Test, issued December 29, 2021;
- Premier Medical Laboratory Services' PMLS SARS–CoV–2 Assay, issued January 7, 2022;
- iHealth Labs, Inc.'s iHealth COVID–19 Antigen Rapid Test Pro, issued January 14, 2022;
- Maxim Biomedical, Inc.'s MaximBio ClearDetect COVID–19 Antigen Home Test, issued January 19, 2022; and
- Mammoth Biosciences, Inc.'s DETECTR BOOST SARS–CoV–2 Reagent Kit, issued January 21, 2022.

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

- EUROIMMUN US, Inc.'s EUROIMMUN Anti-SARS–CoV–2 S1 Curve ELISA (IgG), issued October 4, 2021;
- InBios International, Inc.'s SCoV–2 *Detect* Neutralizing Ab ELISA, issued October 22, 2021.

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

- Laboratory Corporation of America's Labcorp SARS–CoV–2 & Influenza A/B Assay, issued September 30, 2021; [5]
- PerkinElmer, Inc.'s PKamp Respiratory SARS–CoV–2 RT–PCR Panel 1, issued October 6, 2021; [6] and
- Applied BioCode, Inc.'s BioCode CoV–2 Flu Plus Assay, issued December 15, 2021 [7] FDA is hereby announcing the following Authorizations for other medical devices:
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics Collection Kit for COVID–19, issued October 8, 2021; [8]

[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, 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 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 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 the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[6] 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 product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of SARS–CoV–2, influenza A, influenza B, and/or RSV 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 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 product may be effective in diagnosing COVID–19, through the simultaneous qualitative detection and differentiation of RNA from SARS–CoV–2, influenza A virus, influenza B virus, and/or RSV, and that the known and potential benefits of your product when used for diagnosing COVID–19, outweigh the known and potential risks of your product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[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 product may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and

• Audere's *HealthPulse@home,* issued November 30, 2021; [9]

In addition, on September 23, 2021, FDA issued a letter to Developers of Certain Molecular, Antigen and Serology In Vitro Diagnostics (IVDs) Authorized for Emergency Use for Coronavirus Disease 2019 (COVID–19) as of Today's Date (September 23, 2021) for Establishing additional Conditions of Authorization for the EUAs of Certain Molecular, Antigen and Serology IVDs related to viral mutations.[10]

Dated: March 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–06008 Filed 3–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0902]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medication Guides for Prescription Drug Products

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with Medication Guides for prescription drug products.

DATES: Submit either electronic or written comments on the collection of information by May 23, 2022.

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 May 23, 2022. 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 manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2011–N–0902 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medication Guide Requirements for Prescription Drug Product Labeling.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management

transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the 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.

[9] 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 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 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.

[10] FDA concluded that establishing additional conditions on the EUAs within the scope of the 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 to establish the three additional conditions set forth in the letter as permitted by Section 564(e) of the FD&C Act.