Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–15982 Filed 8–5–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcement of the Intent To Award a Single-Source Cooperative Agreement to Burke Law Group, PLLC in Houston, Texas

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of intent to award a single-source cooperative agreement

SUMMARY: The ACF, ORR announces the intent to award a single-source cooperative agreement in an amount of up to $150,000,000 to Burke Law Group, a law firm headquartered in Houston, Texas. The purpose of this proposed award is to provide legal orientation, legal consultation, and attorney-of-record representation services for eligible unaccompanied alien children (UACs) during immigration proceedings before the Executive Office for Immigration Review (EOIR) and in hearings and proceedings before the U.S. Citizenship and Immigration Services (USCIS) while children remain in ORR care. The proposed award also includes limited discharge-related legal continuity planning and referral support for children exiting ORR care. Under the proposed award, Burke Law Group would provide legal orientation, legal consultation, and attorney-of-record representation services for eligible UACs while they remain in ORR care. The recipient would also provide limited discharge-related legal continuity planning and referral support to assist children in connecting with appropriate post-discharge legal resources.

DATES: The proposed period of performance is August 15, 2026 to August 14, 2027.

FOR FURTHER INFORMATION CONTACT: Reina Byrd, Assistant Deputy Director, Unaccompanied Alien Children Bureau, 330 C St SW, Washington, DC 20201. Telephone: (202) 256–9497, *Reina.Byrd@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: ORR announces the intent to award a single-source cooperative agreement to Burke Law Group to provide legal orientation, legal consultation, and attorney-of-record representation services, as required under 8 U.S.C. 1232(c)(5), 45 CFR 410.1309(a), and the preliminary injunction in *Community Legal Services In East Palo Alto, et. al.* v. *HHS, et. al.,* No. 4:25-cv-02847 (N.D. Cal.), for eligible UACs during immigration proceedings before EOIR and in hearings and proceedings before USCIS while children remain in ORR care. The proposed award also includes limited discharge-related legal continuity planning and referral support.

The proposed award would expand ORR's capacity to provide legal orientation, legal consultation, and attorney-of-record representation services for eligible UACs while complementing existing ORR-funded legal services. Services under the proposed award include legal orientation, legal consultation, and attorney-of-record representation during immigration proceedings before EOIR and USCIS, and limited discharge-related legal continuity planning and referral support.

The proposed award is intended to help address identified gaps in legal orientation, legal consultation, and attorney-of-record representation services for eligible UACs while supporting ORR's statutory responsibility to ensure, to the greatest extent practicable, that eligible UACs have counsel to represent them during immigration proceedings.

Statutory Authority: Section 462 of the Homeland Security Act of 2002, 6 U.S.C. 279, transferred responsibility for the care and custody of UACs to the Office of Refugee Resettlement. In addition, the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, 8 U.S.C. 1232(c)(4) and (c)(5), requires the Department of Health and Human Services, to the greatest extent practicable and consistent with 8 U.S.C. 1362, to ensure that UACs have counsel to represent them in legal proceedings or matters and to protect them from mistreatment, exploitation, and trafficking.

Dawnisha Helland,

Assistant Principal Deputy Director, Unaccompanied Alien Children Bureau, Office of Refugee Resettlement.

[FR Doc. 2026–16081 Filed 8–4–26; 4:15 pm]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7956]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of Mpox. FDA has issued an Authorization for an in vitro diagnostic device, Allplex HSV–1&2/VZV/MPXV Assay, for the simultaneous qualitative detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II)1, herpes simplex virus type 1 (HSV–1), herpes simplex virus type 2 (HSV–2), and varicella-zoster virus (VZV). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (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 monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is listed in this document, and can be accessed on FDA's website from the link indicated.

DATES: The Authorization is effective as of July 9, 2026.

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. 5441, 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 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 biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

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 in an actual or potential emergency 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 sections 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) of the FD&C Act, 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.

III. The Authorization

The Authorization follows the August 9, 2022, 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 monkeypox virus. Notice of the Secretary's determination was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to section 564

[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.

of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on September 13, 2022 (87 FR 56074). On July 9, 2026, having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA issued an EUA to Seegene USA, Inc. for the Allplex HSV–1&2/VZV/MPXV Assay subject to the terms of the Authorization. The Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent revision to the Authorization can be found from FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is 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.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

July 09, 2026

Sharon Young
Senior Manager Regulatory Affairs
Seegene USA, Inc.
141 Innovation Drive
Irvine, CA 92617

Device:	Allplex HSV-1&2/VZV/MPXV Assay
EUA Number:	EUA250001
Company:	Seegene USA, Inc.
Indication:	This test is authorized for the simultaneous qualitative detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II)[1], herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of viral infection consistent with mpox[2] by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Sharon Young:

This letter is in response to your[3] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

[1] On August 12, 2022, following a meeting convened by the World Health Organization (WHO) monkeypox virus variants were renamed to align with current best practices under the International Classification of Diseases and the WHO Family of International Health Related Classifications (WHO-FIC). This letter will refer to the former Congo Basin (Central African) clade as clade one (I) and the former West African clade as clade two (II). Refer to: https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names.

[2] On November 28, 2022, following a series of consultations with global experts, the World Health Organization (WHO) began using a new preferred term "mpox" as a synonym for monkeypox, the disease cause by the monkeypox virus. Refer to: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease.

[3] For ease of reference, this letter will use the term "you" and related terms to refer to Seegene USA, Inc.

[4] For ease of reference, this letter will use the term "your product" to refer to the Allplex HSV-1&2/VZV/MPXV Assay used for the indication identified above.

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined 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 United States citizens living abroad that involves monkeypox virus.[5] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on September 7, 2022 that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use." Viral infections caused by MPXV, HSV-1, HSV-2, and VZV can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect monkeypox virus, information from a test that detects and differentiates the virus that causes mpox and HSV-1, HSV-2 and VZV viruses is needed. There is an FDA-cleared test for the qualitative detection of non-variola *Orthopoxvirus*, that includes monkeypox virus, but this is not an adequate and available alternative to your product.[7]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The monkeypox virus can cause a serious or life-threatening disease or condition, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, through the simultaneous qualitative detection and differentiation of monkeypox virus (MPXV clade I/II and MPXV clade II), herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) DNA, and that the known

[5] 87 FR 50090 (August 15, 2022)

[6] 87 FR 56074 (September 13, 2022)

[7] To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558) is the only test available in the United States with FDA clearance for the detection of non-variola *Orthopoxvirus* DNA, including vaccinia, cowpox, monkeypox and ectromelia viruses at varying concentrations. Available information indicates that timely detection of mpox cases in the United States requires wide availability of diagnostic testing to control the spread of this contagious infection and there is currently a need for additional diagnostic testing for monkeypox virus in the United States.

and potential benefits of your product when used for diagnosing infection with the monkeypox virus, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[8]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a multiplex real-time polymerase chain reaction (PCR) in vitro diagnostic test (IVD) intended for the simultaneous qualitative detection and differentiation of viral nucleic acid from monkeypox virus (MPXV clade I/II and MPXV clade II), herpes simplex virus type 1 (HSV-1), herpes simplex virus type 2 (HSV-2), and varicella-zoster virus (VZV) in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of viral infection consistent with mpox by their healthcare provider. Symptoms due to MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, and VZV infection can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

The device is not intended for use with cerebrospinal fluid or for prenatal screening.

The assay detects and differentiates the presence of MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, and VZV viral nucleic acid targets. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results are indicative of the presence of MPXV clade I/II and/or MPXV clade II, HSV-1, HSV-2, or VZV nucleic acid but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results obtained with this device do not preclude MPXV clade I/II, MPXV clade II, HSV-1, HSV-2, or VZV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Your product, is to be used with the Seegene STARlet System (or other authorized system as may be requested under Condition O. below) which automates nucleic acid extraction and PCR plate setup, and the Bio-Rad CFX Opus 96 Dx instrument (or other authorized real-time PCR instrument as may be requested under Condition O. below) for detection and differentiation of the monkeypox virus (MPXV clade I/II and MPXV clade II), HSV-1, HSV-2, and/or VZV nucleic acid targeted sequences using real-time PCR assays, as described in the authorized labeling (described below). The Allplex HSV-1&2/VZV/MPXV Assay includes the materials (or

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

other authorized materials as may be requested under Condition O. below) described in the authorized labeling (described below).

Your product requires control materials (or other authorized control materials as may be requested under Condition O. below) that are described in the authorized labeling. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the authorized labeling.

The labeling entitled "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), and the following fact sheets pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Seegene USA, Inc. – Allplex HSV-1&2/VZV/MPXV Assay
- Fact Sheet for Patients: Seegene USA, Inc. – Allplex HSV-1&2/VZV/MPXV Assay

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing infection with the monkeypox virus, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality management system requirements under 21 CFR Part 820, which incorporates by reference ISO 13485:2016, with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding those parts of 21 CFR Part 820 which incorporates by reference ISO 13485:2016 that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to: ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Seegene USA, Inc. (You) and Authorized Distributor(s)[9]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. Your product must comply with those parts of 21 CFR Part 820, which incorporates by reference ISO 13485:2016, that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to: ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

E. You and authorized distributor(s) must include a physical copy of the authorized "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use" with each shipped product to authorized laboratories and must make the authorized "Allplex HSV-1&2/VZV/MPXV Assay Instructions for Use," electronically available.

F. You and authorized distributor(s) must inform authorized laboratories and relevant

[9] "Authorized Distributor(s)" are identified by you, Seegene USA, Inc., in your EUA submission as an entity allowed to distribute your product.

public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

G. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which your product is distributed and the number of your product distributed.

H. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov).

I. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Seegene USA, Inc. (You)

J. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

K. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

L. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

M. If requested by FDA, you must submit associated documents and records related to your quality management system for FDA review within 48 hours of the request.

N. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

O. You may request modifications to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for modification to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA.

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit lot release procedures to FDA within 48 hours of the request, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S.

R. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) if requested by FDA.[10] After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

S. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.

T. You must evaluate the impact of monkeypox viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

V. You must further evaluate the clinical performance of your product using fresh natural clinical specimens in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

W. If requested by FDA, you must submit records within 48 hours of the request of the instrument qualification procedures performed to verify that the RUO instruments authorized with your product are capable of performing the Allplex HSV-1&2/VZV/MPXV Assay with sufficient accuracy at authorized laboratories, as stated in the authorized labeling.

[10] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

X. You must submit to DMD/OHT7/OPEQ/CDRH within 3 months of the date of this letter your plan and anticipated timeline to establish and maintain a quality management system that is appropriate for your product's design and manufacture, and that meets the requirements of 21 CFR Part 820.

Authorized Laboratories

Y. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Z. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

AA. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

BB. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

CC. Authorized laboratories must have a process in place to track adverse events and report to you (Customer Support: support.seegeneusa@seegene.com) and to FDA pursuant to 21 CFR Part 803.

DD. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling your product, and use your product in accordance with the authorized labeling.

Seegene USA, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

EE. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (via email: support.seegeneusa@seegene.com).

FF. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Page 9 – Sharon Young, Seegene USA, Inc.

Conditions Related to Printed Materials, Advertising and Promotion

GG. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

HH. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of monkeypox virus or other non-variola orthopoxviruses.

II. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories;
- This product has been authorized only for the detection and differentiation of nucleic acid from monkeypox virus, herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus, not for any other viruses or pathogens; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

Page 10 – Sharon Young, Seegene USA, Inc.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15964 Filed 8–5–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0038]

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to their Microbiological Effects on Bacteria of Human Health Concern; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #152 entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' This guidance document informs interested parties about FDA's current method for evaluating potential microbiological effects of antimicrobial new animal drugs on bacteria of human health concern as part of the new animal drug application process.

DATES: The announcement of the guidance is published in the **Federal Register** on August 6, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 the Docket No. FDA–1998–D–0038 for ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' Received comments 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 Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ron Miller, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–0795, *ron.miller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2003, FDA issued GFI #152, entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' GFI #152 outlines a qualitative risk assessment methodology as a process for evaluating foodborne antimicrobial resistance concerns related to the use of antimicrobial drugs in food-producing animals. GFI #152 also contains an appendix, commonly referred to as ''Appendix A,'' in which FDA ranks antimicrobial drugs according to their relative importance to human medicine: ''critically important,'' ''highly important,'' or ''important.'' As stated in the guidance, the drug/drug class rankings provided in the Appendix are intended specifically to inform one component of the described qualitative risk assessment methodology, and they are not intended to be used as a standalone guide for antimicrobial use in veterinary practice or otherwise to serve as a standalone risk management tool.

The list, as published in 2003, of medically important antimicrobial drugs