III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14717 Filed 7–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0249]

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) 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, Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set as requested by the Centers for Disease Control and Prevention (CDC). 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, and can be accessed on FDA's website from the link indicated in Section III. Authorization.

DATES: The Authorization is effective as of March 22, 2024.

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 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, 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,

[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.

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 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 March 22, 2024, 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 CDC, for the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set, 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 from: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

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[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.

U.S. FOOD & DRUG ADMINISTRATION

March 22, 2024

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Device:	Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set - EUA
EUA Number:	EUA230054
Company:	Centers for Disease Control and Prevention (CDC)
Indication:	This test is authorized for the presumptive qualitative detection of DNA from non-variola *Orthopoxvirus* in human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Centers for Disease Control and Prevention designated laboratory from individuals suspected of mpox[1] by their healthcare provider. This test is also authorized for use with acceptable human pustular or vesicular rash specimens collected using authorized home specimen collection kits that are indicated for use with the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA when used consistent with their authorization. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

[1] 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.

Dear Dr. Cohen:

This letter is in response to your[2] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[3, 4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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 EUA Summary (identified below).

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:

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[2] For ease of reference, this letter will use the term "you" and related terms to refer to Centers for Disease Control and Prevention (CDC).

[3] For ease of reference, this letter will use the term "your product" to refer to the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA used for the indication identified above.

[4] The Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set has a granted De Novo and also received marketing clearances from FDA under section 510(k) of the Act (Product Code: PBK; DEN070001, K181205, K221658, K221834, K222558). This emergency use authorization authorizes certain modifications to the procedure and uses that are not under the cleared indications for use of the product and are an "unapproved use of an approved product" under section 564(a)(2)(B) of the FD&C Act. This letter only applies to the emergency use of the Non-variola Orthopoxvirus Real-time PCR Primer and Probe Set -EUA. To date, the FDA-cleared CDC Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set 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 the virus that causes mpox in the United States.

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

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

1. The virus that causes mpox 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 virus that causes mpox, and that the known and potential benefits of your product when used for diagnosing infection with this 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.[7]

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 a real-time PCR test intended for the presumptive qualitative detection of DNA from non-variola *Orthopoxvirus* in human pustular or vesicular rash specimens and viral cell culture lysates submitted to a Centers for Disease Control and Prevention designated laboratory from individuals suspected of monkeypox virus infection by their healthcare provider. Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity testing.

This test is also authorized for use with acceptable human pustular or vesicular rash specimens collected using authorized home specimen collection kits that are indicated for use with the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA when used consistent with their authorization.

Results are for the identification of non-variola *Orthopoxvirus* DNA. This assay does not differentiate vaccinia virus or monkeypox virus from other orthopoxviruses detected by this assay and does not detect variola virus. The non-variola *Orthopoxvirus* DNA is generally detectable in human pustular or vesicular rash specimens and viral cell culture lysates during the acute phase of infection. Refer to the CDC algorithms, *Acute, Generalized Vesicular or Pustular Rash Illness Testing Protocol and Evaluating Patients for Smallpox: Acute, Generalized Vesicular or Pustular Rash Illness Protocol in the United States* for recommended testing and evaluation algorithms for patients presenting with acute, generalized pustular or vesicular rash illness. These results must be used in conjunction with other diagnostic assays and clinical observations to diagnose Orthopoxvirus infection.

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

To use your product, non-variola *Orthopoxvirus* nucleic acid is first extracted, isolated and purified from human pustular or vesicular rash specimens and viral cell culture lysates followed by PCR amplification and detection using an authorized RT-PCR instrument described in the authorized labeling (described below). The Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA includes the materials (or other authorized materials as may be requested under Condition N. below) described in the authorized labeling (described below).

Your product requires control materials (or other authorized control materials as may be requested under Condition N. below) that are described in both of the authorized labeling (described below). 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 described below.

The above described product is authorized to be accompanied by the EUA summary, (available at https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices), the "Detection of Non-variola *Orthopoxvirus* DNA using the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA with the ThermoFisher QuantStudio 7 Flex (QS7) PCR Instrument" and the "Extraction of *Orthopoxvirus* DNA using the KingFisher Flex Instrument for Use With the Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set – EUA" laboratory Standard Operating Procedures (SOPs), 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: Centers for Disease Control and Prevention (CDC) – Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA
- Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) – Non-variola *Orthopoxvirus* Real-time PCR Primer and Probe Set -EUA

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 system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

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

Centers for Disease Control and Prevention (CDC) (You) and Authorized Distributor(s)[8]

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 the following quality system requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

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

[8] "Authorized Distributor(s)" are identified by you, Centers for Disease Control and Prevention (CDC), in your EUA submission as an entity allowed to distribute your product.

D. You and authorized distributor(s) must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

F. 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.

G. 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.

Centers for Disease Control and Prevention (CDC) (You)

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

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

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

K. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

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

M. 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).

N. 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 the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA.

O. 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.

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

Q. 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.[9] After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing if requested by FDA. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

R. You must have a process in place to track adverse events, including with any authorized home specimen collection kits, and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

S. 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).

T. 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.

Authorized Laboratories

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

V. 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.

[9] 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.

W. 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.

X. 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.

Y. Authorized laboratories using your product must maintain records of the use of any authorized Research Use Only (RUO) reagent kits, including lot numbers, when testing patient specimens.

Z. Authorized laboratories using your product must include positive and negative controls in every specimen run using authorized RUO reagent kits and/or instruments.

AA. Authorized laboratories using your product must evaluate the use of each authorized RUO extraction platform, authorized RUO instrument and/or each lot of authorized RUO reagent kit(s) using standard laboratory protocols in each laboratory for reagent lot and instrument qualification in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. § 263a) and implementing regulations to confirm that instruments and reagents are suitable for use with your product and to verify the performance of your product with each lot.

BB. Authorized laboratories testing authorized specimens collected using an authorized home specimen collection kit that are indicated for use with your product must follow any specimens accessioning protocols provided with the authorized home specimen collection kit when accepting specimens for testing.

CC. Authorized laboratories must have a process in place to track adverse events, including with any authorized home specimen collection kits, and report to you (via email: poxviruslab@cdc.gov) and to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

DD. All laboratory personnel using your product must be appropriately trained in real-time PCR techniques and use appropriate laboratory and personal protective equipment when handling your product and use your product in accordance with the authorized labeling.

Centers for Disease Control and Prevention (CDC) (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: poxviruslab@cdc.gov).

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.

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 of nucleic acid from non-variola orthopoxviruses, including monkeypox 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 – Mandy K. Cohen, MD, MPH, Centers for Disease Control and Prevention (CDC)

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,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2024.03.22 10:16:17 -04'00'

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

Dated: July 1, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3196; FDA–2023–E–3198; and FDA–2023–E–3199]

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

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 IMJUDO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 biological 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 September 3, 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 January 2, 2025. 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 September 3, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 the Docket Nos. FDA–2023–E–3196; FDA–2023–E–3198; and FDA–2023–E–3199 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; IMJUDO.'' 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