

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.

FOR FURTHER INFORMATION CONTACT: Kyong “Kaye” Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–1970, Kyong.Kang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Alzheimer’s disease (AD) is a major public health concern worldwide and its accurate diagnosis and staging is critical for the optimal management of patients at risk for or afflicted with this devastating disorder. The accuracy of

clinical diagnosis of AD by dementia experts is modest when compared to postmortem diagnosis. Amyloid burden is one of the pathological hallmarks of the disease, and in patients presenting with cognitive and memory disturbances, quantitative imaging of brain amyloid offers the potential to enhance the assessment and management of patients with suspected or confirmed AD. This workshop aims to evaluate the role of quantitative PET measures of amyloid deposition in the brain in clinical trials and as well as in clinical use in patients with suspected or confirmed AD.

II. Topics for Discussion at the Public Workshop

The workshop will provide an overview of clinical and investigational uses of brain amyloid PET imaging, the regulatory history of marketed imaging drug products and devices for amyloid quantitation, clinical pharmacology of tracers, quantitation methodology, metrics and analytical validity, and use of quantitative amyloid in clinical trials with perspectives from industry, trade and professional organizations, academic investigators, and patient advocacy group.

III. Participating in the Public Workshop

Registration: To register for the public workshop, persons interested in attending this public workshop virtually or in-person must register online by November 16, 2022, 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. No same-day registration will be available.

Registration is free and in-person participation is limited due to space availability constraints; therefore, FDA may limit the number of onsite participants from each organization. Registrants will receive confirmation when they have been accepted. If there are COVID–19 restrictions in place at the time of the event, this conference will move to an all-virtual event.

If you need special accommodations due to a disability, please contact Kyong “Kaye” Kang no later than November 16, 2022.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at https://fda.zoomgov.com/webinar/register/WN_ezA_Y94QMSaT0SHBdlS5g.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro

program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/drugs/news-events-human-drugs/fda-cder-cdrh-snmml-and-mita-workshop-quantitative-brain-amyloid-pet-imaging-patients-alzheimers>.

Dated: October 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23380 Filed 10–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1959]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; postponement of meeting.

SUMMARY: The Food and Drug Administration (FDA) is postponing the joint meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee scheduled for November 18, 2022. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Moon Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2894, NDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: The joint meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs

Advisory Committee was originally announced in the **Federal Register** of September 13, 2022 (87 FR 56071). The meeting has been postponed to allow time for FDA to review new information. Future meeting dates will be announced in the **Federal Register**.

Dated: October 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-23379 Filed 10-26-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2375]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Monkeypox Virus; 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 monkeypox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Abbott Molecular, Inc. 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 reprinted in this document.

DATES: The Authorization is applicable as of October 7, 2022.

ADDRESSES: Submit written requests for a single copy of the 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 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 public health protections against biological, chemical, nuclear, and radiological 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, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

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, 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).

II. Criteria for EUA Authorization

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

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.