The main benefits that Intarcia highlights relate to its position that ITCA 650 is a valuable new dosing option because it may increase medication adherence. Intarcia has not provided data in support of its argument but instead bases this assertion on the fact that ITCA–650 is an implantable device that lasts for 3 or 6 months. However, the evidence offered in support of approval undermines Intarcia's position. As previously discussed, ITCA 650 has dose reliability and variability issues. As previously outlined in the EMDAC discussion summary, multiple EMDAC members expressed concern that the drug delivery variability issue could lead to patients receiving less reliable drug doses than if they were using an analogous drug regimen that was not delivered via an implanted osmotic pump. Therefore, if ITCA 650 does not provide the proper dose, a patient would become nonadherent to their medication, regardless of the patient's intentions. The PDC therefore disagrees with Intarcia and its experts that the mode of drug delivery inherently equates to medication adherence. Furthermore, as found by CDER in its proposed order, ''Intarcia has provided no evidence that demonstrates patients prescribed ITCA 650 are more likely to continue the treatment than patients prescribed other approved treatments for type 2 diabetes.'' Given the lack of concrete information to support its theoretical argument, the PDC gives little weight to this benefit in the overall assessment of whether the benefit-risk assessment supports approval of ITCA 650 in its present form.

D. Conclusion

While Intarcia correctly points out in its appeal that more therapies are needed for patients with T2DM, FDA will only approve NDAs when the data shows that the benefits outweigh the risks. After reviewing the information contained in the public record, the PDC finds that the benefits of ITCA 650 do not outweigh its risks. The PDC agrees with the EMDAC's conclusions and find that there are too many unanswered questions regarding risks associated with ITCA 650 to find that it has a positive benefit-risk profile and is safe under section 505(d)(2) of the FD&C Act. For the reasons described above, Intarcia has not presented adequate evidence to show that the drug is safe for use under the proposed conditions; therefore, the PDC cannot approve the NDA for ITCA 650.

IV. Findings and Order

For the reasons described above, FDA finds that the record shows that the approval criteria set forth in section 505(d)(2) of the FD&C Act have not been met, as ITCA 650's risks outweigh its benefits; therefore, Intarcia has not demonstrated that ITCA 650 is safe for its intended use. Therefore, under section 505(d) of the FD&C Act, FDA hereby denies approval to Intarcia's NDA in its current form.

Dated: August 16, 2024.

Namandjé N. Bumpus,

Principal Deputy Commissioner.

[FR Doc. 2024–18898 Filed 8–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to Coronavirus Disease 2019 (COVID–19). FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for

a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from FDA's web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from July 8, 2024, through July 23, 2024, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for multianalyte tests:

- Nano-Ditech Corporation's Nano-Check Influenza+COVID–19 Dual Test, issued on July 08, 2024.[3]
- ACON Laboratories, Inc.'s Flowflex Plus COVID–19 and Flu A/B Home Test, issued on July 23, 2024.[4]

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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[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.

[3] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus, and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[4] As set forth in the EUA for this product, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus and/or influenza B virus protein antigens, and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.