ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Annual number of responses per respondent	Average annual burden hours per response	Annual burden hours
Applications for the purchase, construction, or renovation of facilities; record retention and submission of documents on facilities	250	1	40	10,000
Waiver request	200	1	1	200
Up-to-date child rosters and lists of adults each child is authorized to be released to are maintained	2,900	1	2	5,800
Agencies required to compete will have to complete an application for each grant competed	75	1	60	4,500
Each Head Start or Early Head Start agency wishing to be renewed for 5 years without competition shall request that status from ACF	400	1	0.25	100
Updating program and personnel policies and procedures that promote implementation of Head Start standards	2,900	1	7	20,300

Estimated Total Annual Burden Hours: 2,476,243.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 641A of the Head Start Act, 42 U.S.C. 9836A.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–10682 Filed 5–15–24; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to 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 the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from December 9, 2023, through April 19, 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 molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- Tetracore, Inc.'s, EZ–SARS–CoV–2 Real-Time RT–PCR, issued March 19, 2024; and
- LMSI, LLC d/b/a Lighthouse Lab Services, SalivaNow SARS–CoV–2 Assay, issued on April 1, 2024.

FDA is hereby announcing the following Authorizations for multianalyte tests:

- SEKISUI Diagnostics, LLC's OSOM Flu SARS–CoV–2 Combo Home Test, issued on February 29, 2024.[4]

[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 EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the 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.

• SEKISUI Diagnostics, LLC's OSOM Flu SARS–CoV–2 Combo Test, issued on February 29, 2024.[5]

• CorDx, Inc.'s, CorDx Tyfast Flu A/B & COVID–19 Multiplex Rapid Test, issued on March 21, 2024;[6]

• OSANG LLC's OHC COVID–19/Flu Antigen Test Pro, issued on March 21, 2024.[7]

• OSANG LLC's QuickFinder COVID–19/Flu Antigen Self Test, issued on April 3, 2024.[8]

• CorDx, Inc.'s CorDx TyFast Flu A/B & COVID–19 At Home Multiplex Rapid Test, issued on April 5, 2024;[9] and

• Wondfo USA Co., Ltd.'s WELLlife COVID–19/Influenza A&B Test, issued on April 19, 2024.[10]

Dated: May 13, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10717 Filed 5–15–24; 8:45 am]

BILLING CODE 4164–01–P

[5] 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.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

[10] 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2178]

Helsinn Healthcare SA; Withdrawal of Approval of New Drug Application for TRUSELTIQ (Infigratinib Phosphate) Capsules, 25 Milligrams and 100 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for TRUSELTIQ (infigratinib phosphate) Capsules, 25 milligrams (mg) and 100 mg, held by Helsinn Healthcare SA, C/O Helsinn Therapeutics (U.S.), Inc. (Helsinn), 200 Wood Ave. South, Suite 100, Iselin, NJ 08830. Helsinn has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 16, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 28, 2021, FDA approved NDA 214622 for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (advanced bile duct cancer or advanced cholangiocarcinoma) with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, for advanced bile duct cancer or advanced cholangiocarcinoma included required postmarketing trials intended to verify the clinical benefit of TRUSELTIQ.

On October 5, 2022, Helsinn voluntarily requested withdrawal of approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg. On February 15, 2023, FDA recommended that the applicant submit a letter to voluntarily request withdrawal of approval of TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, according to § 314.150(d) (21 CFR 314.150(d)) due to the company's inability to conduct a clinical trial to verify clinical benefit. On April 21, 2023, FDA requested Helsinn waive its opportunity for a hearing.

On May 30, 2023, Helsinn submitted a letter asking FDA to withdraw approval of NDA 214622 for TRUSELTIQ (infigratinib phosphate) Capsules, 25 mg and 100 mg, according to § 314.150(d) and waiving its opportunity for a hearing. In its letter requesting withdrawal of approval, Helsinn stated that it is voluntarily requesting withdrawal due to difficulties in recruiting and enrolling study subjects for the required confirmatory clinical trial in first line cholangiocarcinoma (a new indication under investigation for TRUSELTIQ), and the determination that, as a result, continued distribution of TRUSELTIQ in second line cholangiocarcinoma (the accelerated approval indication) is not commercially reasonable. Helsinn stated