U.S. FOOD & DRUG ADMINISTRATION

September 10, 2023

Christine P. Bump
[redacted]

Sent via email to: [redacted]

Re: Docket Number FDA-2020-P-2060

Dear Petitioner:

This letter responds to your citizen petition, dated October 7, 2020, and filed by the Food and Drug Administration (FDA, we, or the Agency) on October 8, 2020.

In your petition, you request that FDA take administrative action with respect to certain tests for Coronavirus Disease 2019 (COVID-19) during the public health emergency (PHE). Specifically, you request that during the PHE, FDA take action to permit facilities to use screening tests, including molecular in vitro tests, to improve facilities' ability to prevent COVID-19 transmission. FDA provided an interim response to your petition on May 10, 2021.

We have carefully considered the issues raised in your petition and interpreted your request, listed above, to be a request for FDA to take administrative action regarding testing for COVID-19 during the PHE. There have been changes in circumstances since the date on which the petition was submitted, which render your petition moot. Therefore, FDA is dismissing your petition as moot under 21 CFR 10.30(e).

Discussion:

The portion of your petition that requests FDA take administrative action during the PHE is moot. In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. The virus was named "SARS-CoV-2," and the disease it causes is COVID-19. On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a determination of a PHE related to COVID-19 in accordance with section 319 of the Public Health Service Act (hereinafter referred to as "section 319 PHE declaration"). The section 319 PHE declaration related to COVID-19 expired on May 11, 2023. Therefore, the portion of your request that asks FDA to take administrative action during the PHE is no longer relevant.

The portion of your petition that requests that FDA take action to permit facilities to use screening tests, including noninvasive or minimally invasive molecular in vitro screening tests, under the same policy that surveillance tests are permitted to improve facilities' ability to prevent

COVID-19 transmission is also moot. Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA,[1] after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use (EUA), to authorize the emergency use of an unapproved product or an unapproved use of an approved product for certain emergency circumstances. FDA may issue an EUA to allow a product to be used to diagnose, treat, or prevent a serious or life-threatening disease or condition referenced in the EUA declaration, when the statutory criteria are met, including FDA's determination that, based on the totality of scientific evidence, the product may be effective for such use, the known and potential benefits outweigh the known and potential risks for such use, and that there are no adequate, approved, and available alternatives. An EUA issued under section 564 of the FD&C Act remains in effect for the duration of the relevant EUA declaration, unless FDA chooses to revoke the EUA because the criteria for issuance are no longer met or revocation is appropriate to protect public health or safety. An EUA declaration under section 564 of the FD&C Act is distinct from, and is not dependent on, a declaration by the HHS Secretary of a PHE under section 319 of the PHS Act.

In response to the PHE, FDA authorized the emergency use of certain devices under section 564 of the FD&C Act. Since the date of your petition, for example, FDA authorized the first over-the-counter antigen test as a fully at home diagnostic test for COVID-19 in December, 2020. A list of tests authorized under an EUA is available here: In Vitro Diagnostics EUAs | FDA. The device EUAs related to COVID-19 remain in effect until the relevant EUA declaration under section 564 of the FD&C Act is terminated or FDA otherwise revokes a specific EUA, even if the section 319 PHE declaration related to COVID-19 expires before then.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.09.10 16:30:40 -04'00'

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

[1] The Secretary of Health and Human Services (Secretary) redelegated to the Commissioner of Food and Drugs, with authority to redelegate (except when specifically prohibited), all authority functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended. https://www.fda.gov/media/81983/download.

U.S. Food & Drug Administration
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