August 4, 2021

Dr. S. Albert Edwards
(b) (6)

Sent via email to: (b) (6)
Re: Docket No. FDA-2020-P-2237

Dear Dr. Edwards:

This responds to the citizen petition received by Food and Drug Administration (FDA or the Agency) on November 25, 2020. Your petition requests that FDA set time limits for Emergency Use Authorizations (EUAs) for regulated medical products within FDA's jurisdiction. We appreciate your interest in FDA's emergency response authorities. After review of the grounds upon which you base your petition and for the reasons stated below, we deny your request to set time limits as a general matter for EUAs.

The following responds to your "Statement of Grounds" for requesting FDA to set time limits.

First, you state: "FDA, via its internal records, has a rich history of the time required for the development of regulated Medical Products" that FDA should apply to set time limits for classes of product (e.g., devices, drugs, vaccines). It is unclear what internal records are contemplated as each product within any class of product has its own development trajectory which depends upon many factors (e.g., experience of the developer, FDA experience with the product for other non-emergency uses or with the platform or technology, developer reliance on previously submitted and reviewed data and/or information, etc.). There are no internal development records that exist that would inform the time to development that could be extrapolated to classes of products. Setting an arbitrary time limit would not serve the public interest of facilitating access to necessary medical products during emergencies.

Second, you state that by FDA applying a reasonable timetable for an EUA, developers will be incentivized to continue development of their product to approval/clearance. You refer to "FDA's Watchdog Role"[1] for drug products, suggesting that FDA treats drug products differently than other regulated medical products, specifically pointing out that "[t]he benefit/risk of a medical test deserves the same type of 'Gold Standard' review and evaluation by FDA as does a drug or device." If a manufacturer intends to commercially market its product after the EUA is no longer in effect for non-emergency uses, FDA works with the manufacturer as appropriate regardless of product type. In fact, FDA is required to review the circumstances and

[1] Please note that all the links provided within the Citizen Petition to support your statements are broken.

appropriateness of an EUA periodically, including progress made with respect to the approval of the product.[2] With regard to tests in particular, FDA works closely with industry, laboratories, non-governmental organizations, and government partners to understand the challenges with advancing EUA tests toward full marketing status.[3] Based on these engagements and without other evidence to the contrary, we do not believe imposing time limits on the duration of an EUA would provide additional incentive to further advance tests toward approval/clearance.

Third, you state "It is more likely than not that FDA's enforcement tasks will lessen with the application of the aforementioned timelines." Unfortunately, FDA has found that unscrupulous actors are opportunistic and engage in fraudulent activities during public health emergencies.[4] You have not presented, nor is FDA aware of evidence to suggest that time limits on EUAs would curb the activity in question.

Fourth, you state "FDA has successfully implemented timelines in conjunction with regulated industry," seemingly equating PDUFA[5] and MDUFA[6] goals (which set timelines for review and approval/clearance of certain applications) with a time limit on the approval of the product itself. The referenced timelines do not impose time limits on the approval or clearance of the product; once approved/cleared, legally marketed products have no time limits. For an EUA, the time to issuance is determined by the emergency circumstances and in some cases can be within hours or days of a request. While there is no set time limit for the duration of an authorization, there is a statutorily based revocation process,[7] which not only appropriately sets manufacturer expectations that the authorization is temporary, but also allows FDA to revoke EUAs based on the changing circumstances of the emergency and public health and safety needs.[8]

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[2] Section 564(g)(1) of the Federal Food Drug and Cosmetic (FD&C) Act. See also, FDA's guidance document *Emergency Use Authorization of Medical Products and Related Authorities* (EUA guidance) at https://www.fda.gov/media/97321/download.

[3] For example, in coordination with the Medical Device Innovation Consortium, FDA held a workshop on February 3, 2020, brief summary and overview at: MDIC-FDA Workshop: Advancing EUA IVD Products Toward Full Marketing Status - MDIC.

[4] See FDA's website listing FDA issued warning letters and reports of unlawful sales of medical products on the internet: https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products.

[5] Prescription Drug User Fee Amendments: https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.

[6] Medical Device User Fee Amendments: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

[7] Section 564(g) of the FD&C Act. Section 564(f) of the FD&C Act provides that the authorization "shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subjection (g)." See also, EUA guidance at https://www.fda.gov/media/97321/download.

[8] For an archival record of revoked EUAs, see: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information.

For these reasons, FDA denies your request to set time limits as a general matter for EUAs.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.08.04 20:16:09 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration