ConnectedHealthInitiative

March 23, 2022

Commissioner Robert Califf
U.S. Food & Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave
Silver Spring, Maryland 20993-0002

RE: ***Connected Health Initiative Comments on the Food and Drug Administration's Draft Guidance on a Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency [Docket No. FDA-2021-D-1149; 86 FR 72978] and a Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency [Docket No. FDA-2021-D-1118; 86 FR 72973]***

Dear Commissioner Califf:

The Connected Health Initiative (CHI) writes to provide input on the Food and Drug Administration's (FDA) draft guidance documents (1) describing the FDA's general recommendations for its transition process with respect to devices issued emergency use authorizations (EUAs) during the COVID-19 Public Health Emergency (PHE), including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to such devices;[1] and (2) describing FDA's general recommendations for a phased transition process with respect to devices that fall within enforcement policies issued during the COVID-19 PHE.[2]

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

CHI advocates for the increased use of new and innovative digital health tools in both the prevention and treatment of disease and we appreciate the FDA's consistent

[1] 86 FR 72978.

[2] 86 FR 72973.

collaboration on digital health-related technologies to responsibly streamline their pathway to the market. CHI is a longtime supporter of the FDA's efforts to modernize and streamline the medical device approval process, particularly for device software functions controlling or part of a hardware device (i.e., Software in a Medical Device, or SiMD) and for devices that are not part of a hardware device (i.e., Software as a Medical Device, or SaMD).

The COVID-19 pandemic has caused unprecedented damage throughout the United States. With an increasingly strained healthcare workforce during this time of crisis, all levels of government must take extraordinary steps to enable access to care for those in need. Early diagnosis of COVID-19, assessment of disease progression, and determining patient prognosis are vital for treatment and enable isolation of infected patients to prevent the spread of this virus has been critical. FDA's many measures taken to date, including approximately 900 authorizations through its EUA pathway, have been central to combating the pandemic. CHI supports FDA's measures taken to address this public health emergency to date and remains committed to assisting the FDA in accomplishing its important mission during this time.

CHI applauds FDA's recognition that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and the FDA to adjust from policies adopted and operations implemented during the declared COVID-19 PHE to normal operations. We also appreciate the large effort required of FDA staff to transition products brought to the market during the PHE to a post-PHE world.

CHI supports this proposed guidance from the FDA and believes that it will greatly assist in the transition process for devices issued EUAs during the COVID-19 PHE. Notably, CHI supports FDA's proposed 180-day transition period for device manufacturers for advance notice of termination of each EUA declaration pertaining to devices, which will allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions. CHI also agrees that FDA's proposed transition policy will help the Agency to satisfy the requirement in section 564(b)(2)(B) of the federal Food, Drug, and Cosmetic Act (FD&C Act) to consult with a manufacturer that was issued an EUA for an unapproved product on the appropriate disposition of the product.

We also offer the following suggestions on ways to improve the proposed guidance:

- FDA's draft guidance appropriately addresses reusable life-supporting devices and notifications of intent for market submissions to enable continued distribution of a product after its EUA ends. While the draft guidance suggests that such notifications of intent be submitted to FDA "as soon as possible" upon finalization of this guidance, the draft indicates that a 90-day period should be provided for such notifications of intent. To avoid any confusion, and to provide a reasonable and consistent period of time for those with EUAs to determine a course of action, we urge FDA to harmonize its guidance to permit a 90-day period from the finalization of this guidance during which notifications of intent for market submissions can be submitted.

- CHI urges FDA to clarify that FDA staff will work with a device manufacturer during the 15-day period after a 501(k) is received/before substantive review to work through any issues that would result in a rejection of the 501(k) marketing application unless corrected. Should the marketing application be rejected, we urge FDA to provide a 60-day period (during which the device manufacturer can interact with FDA staff) for continued medical device distribution, allowing for resolution of any issues that resulted in the rejection and resubmission of the application. This allowance, and access to FDA staff, are key to satisfying 564(b)(2)(B) of the FD&C Act.
- While the draft guidance proposes requiring marketing submission labels be updated to show EUA acceptance while also indicating that no final action has been taken by FDA on the submission, no labeling requirement to indicate regulatory status exists for devices generally pending FDA review. We urge FDA to minimize burdens on device manufacturers who would have to implement such a novel labeling requirement and update patients and healthcare providers (and to update them again upon full approval). Such labeling requirements may add to patient and provider confusion about the status of a device. We urge FDA to remove its proposed requirement for marketing submission labels to be updated to reflect EUA acceptance but also indicate that no final action has been taken by FDA on the submission, and to permit a medical device's regulatory status to be indicated electronically (via website and electronic notification).

CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input.

Sincerely,

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