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BY ELECTRONIC DELIVERY

Dr. Jeffrey E. Shuren MD, JD
Director
Center for Devices and Radiological Health
United States Food and Drug Administration

RE: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the COVID-19 Public Health Emergency Draft Guidance

Dear Dr. Shuren,

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing to provide feedback on the December 2021 draft guidance issued by the Food and Drug Administration (FDA) titled "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

Medical imaging technologies have played an essential role in our nation's health care infrastructure and the care pathways of evaluating, staging, managing, and effectively treating patients with COVID-19.[1] In order to ensure expedient patient access to critical imaging technologies, FDA granted medical imaging device manufacturers certain regulatory flexibilities in an April 2020 final guidance titled "Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

In anticipation of the drawdown of the declared Public Health Emergency and the end of the COVID-19 pandemic, it will be essential that medical device manufacturers have clarity and flexibility regarding how to handle products brought to market under enforcement discretion policies. The transition plan outlined in this draft guidance would give manufacturers a suitable level of clarity and flexibility, and a long enough timeframe to transition devices into normal compliance or off the market.

We applaud the tremendous effort FDA put into managing the COVID-19 pandemic and look forward to continuing to work with the Agency as we move through and beyond this public health emergency.

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[1] https://www.covid19treatmentguidelines.nih.gov/overview/management-of-covid-19/

If you have any questions, please contact Peter Weems, Senior Director, Policy & Strategy, at pweems@medicalimaging.org or 703-841-3238.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.