MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

August 13, 2015
Docket No. FDA- 2010-N-0389

Leslie Kux, Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Medical Device User Fee Amendments; Public Meeting; Request for Comments**

Dear Sir/Madam:

On behalf of the Medical Imaging and Technology Alliance, I am pleased to submit these comments regarding the Medical Device User Fee Amendments Public Meeting. MITA is the leading organization and collective voice of medical imaging equipment, radiation therapy 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. 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 holds unique concerns marked by a continual drive for innovation and marketization cycles, complex technologies, and multifaceted supply chains—all with the goal of providing patients with safest, most advanced medical imaging currently available.

MITA continues our strong support for an effective, well- resourced FDA capable of fulfilling its mission to protect and promote the public health. The medical imaging industry supported enactment of FDA's user fee program in 2002 and its subsequent reauthorizations in 2007 and 2012. We are dedicated to participating in the MDUFA IV negotiations in good faith and are looking forward to working collaboratively with the FDA and Congress throughout this process.

Value of Medical Imaging:
Medical imaging helps detect and diagnose disease at its earliest, most treatable stages and guides physicians and patients in determining the most appropriate and effective care. Our technologies are fundamental to standards of care. By catching disease early, reducing the need for invasive, in-patient procedures and facilitating shorter recovery times, medical imaging saves money and improves efficiency in the health care system. Medical imaging technologies have revolutionized health care delivery in America and around the world. Extending human vision into the very nature of disease, medical imaging enables a new and more powerful generation of diagnosis and intervention.

Over the last 20 years, imaging has contributed to significant advances in healthcare delivery, leading to better health outcomes and reduced costs. For example, 20 years ago, an X-ray was used to detect lung nodules, but was limited in its capacity to detect small nodules. Now, low dose lung computed tomography (CT) finds tiny tumors the size of a grain of rice. This reduces lung cancer deaths by 20%

compared to chest x-ray.

Today, technology that was once unimaginable is now the medical standard of care. The next generation of imaging technologies will further advance healthcare and the practice of medicine. A consistent and timely FDA review process is essential to timely patient access to these devices.

MDUFA III:
User fees provide for a more efficient pre-market clearance process allowing for life-saving devices to get to market more quickly. We firmly believe that user fees represent an effective *supplement* to increase Congressional appropriations for the Agency's medical device program when paired with specific performance goals and commitments from the Agency. This enhanced funding brings stability and predictability to the device review process and timelines. The goals that the medical device industry and FDA agree on and FDA's subsequent performance are critical to timely patient access to safe and effective medical advancements. Without a consistent and timely FDA review process, conducted by a well trained staff, access to new diagnostic imaging equipment is delayed and industry's ability to deliver technological advancements is compromised.

While important strides have been made as a result of the MDUFA program some troubling trends remain in the FDA's device review process. Manufacturers have experienced increased and unpredictable data requests from reviewers and inconsistent use of the interactive review process. These increased requests and inconsistencies have led to longer average times to decision for 510(k)s. The average time to decision on 510(k)s remains above historic averages while the time submitters spend answering FDA requests for more data has increased significantly since the beginning of the MDUFA program.

MDUFA IV:

With this in mind the medical imaging community hopes to advance the following principles for meeting our shared objectives in the MDUFA reauthorization process:

1) Appropriate, measurable, and predictable performance goals;
2) Stable funding for FDA, with users fees serving as an *additive* resource complementing the FDA-appropriated budget;
3) Continuation of the independent assessment process and FDA implementation of recommendations to improve efficiencies; and
4) Availability of additional training and educational resources to keep reviewers apace with changes in medical technology

MITA maintains the performance goals set forth in MDUFA IV must be achievable, with easily understood and transparent metrics. These goals should focus on reducing pre-market review times and improving the consistency of reviews. MITA would like to see continued improvement in consistency with the qualitative goals established in MDUFA III across review divisions and branches.

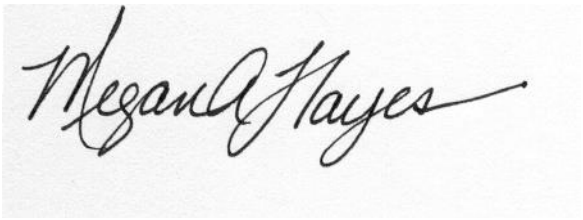
MITA would like to see continued focus on reviewer training, particularly for new hires. Any gaps in statutory or regulatory knowledge and subject matter expertise can manifest in inconsistent application of medical device laws, regulations, and guidance documents. This would be a disservice to the medical device manufacturing community. Qualitative goals for training, industry-FDA meetings, regulatory

science and guidance development must be effectively implemented across all relevant FDA offices involved in device review and guidance development. The increasing velocity of technological change highlights the increasing need for enhanced training and guidance.

Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. MITA looks forward to working collaboratively with FDA and Congress to develop a robust legislative proposal providing improved performance goals and reasonable user fees for value. We are confident these negotiations will result in an agreement leading to an improvement in patient access to safe and effective medical devices. Most importantly we are committed to ensuring the ultimate beneficiaries of these negotiations, the American public, benefit from continued improvements in timely access to the innovative devices and diagnostics necessary for the public health.

Thank you for the opportunity to submit comments on this important agreement. MITA appreciates your consideration of our comments and suggestions. If you have any questions, please feel free to contact me at 703-841-3285 or by email at mhayes@medicalimaging.org.

Respectfully Submitted,



Megan A. Hayes
Director, Regulatory and Standards Strategy