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February 29, 2016

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: Docket No. FDA-2013-N-0242: Agency Information Collection Activities: Proposed Collection; Comment Request; Current Good Manufacturing Practice for Positron Emission Tomography Drugs

Dear Ms Kux:

As the premier trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) is providing comments on the collection of information related to current Good Manufacturing Practices (GMP) for Positron Emission Tomography (PET) drugs.

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MITA believes the published estimates of recordkeeping burden may be materially weak and desire to work with the agency to improve the accuracy of these estimates.

Comments on four topics in the Federal Register Notice:
In the Federal Register Notice, the FDA requested comments on four specific areas related to the recordkeeping burden for PET GMP.

1. Whether the proposed collection of information is necessary for the proper performance of FDA functions, including whether the information will have practical utility.

MITA supports the collection of information and believe it to be important for the proper performance of FDA functions. We believe, however, that a more accurate determination of the recordkeeping requirements will help ensure future decision-making regarding burdens of recordkeeping for PET GMP regulations are more fully informed.

2. The accuracy of FDA estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

MITA is concerned about the accuracy of the estimates based on a review of the data provided in Table 1 (Estimated Annual Record Keeping Burden) and Table 2 (Estimated Annual Third-Party Disclosure Burden). Therefore, MITA respectfully questions the methodology basis of the estimates in Table1 and 2 of the Federal Register Notice and likely their validity. Importantly, several of the estimates significantly

differ from MITA Member company experiences in complying with the recordkeeping requirements. Because of this divergence, MITA requests FDA explore this matter in more detail. MITA desires to assist with the performance of a new survey to help ensure the accuracy of the data and in such other ways may be useful.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

MITA believes that the quality, utility, and clarity of the information to be collected can be enhanced by directly involving MITA Member companies in establishing the estimates. MITA companies include all three national commercial distribution networks, representing 80+ PET drug manufacturing sites, and would provide a robust empirical basis upon which to craft a high-fidelity estimate of record-keeping burden. The existing estimates were originally developed when the Final Rule for the PET GMP regulations was published. [1]

At the time, there was insufficient experience with PET drug manufacturing to develop accurate estimates. Now, with the benefit of almost 4 years of FDA regulation, PET drug manufacturers are in a position to make accurate assessments which in turn would contribute uniquely to the FDA estimates.

4. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

MITA companies have real-world experience and would appreciate the opportunity to work with the Agency to identify ways to minimize the burden of the collection of information on respondents.

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We look forward to working with FDA to help improve the accuracy of recordkeeping burden for current PET GMP. If you have any questions, please contact Terri Wilson at 314-365-6731 or by email at twilson@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director
Medical Imaging & Technology Alliance

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, radiation therapy equipment, 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.

[1] 74 Federal Register65409, 65430 (December 10, 2009). See: Docket no. FDA–2004–N–0449 (formerly 2004N–0439).