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June 6, 2022

Via Electronic Submission

Ms. Lauren K. Roth
Associate 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. Roth,

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. With respect to the specific information for which the FDA has invited comment, please find MITA's responses in bold below.

1. Proposed collection of information is necessary for FDA's functions – **MITA has no comment.**

2. Accuracy of FDA's estimate of the burden of the proposed collection of info, including the methodology and assumption validity
    a. **One-time burden - Creation of procedures does not take into account time for the approval process, which requires multiple disciplines to review and approve the record. Also, it appears that the following are significantly underestimated or not included:**
        1. Analytical Method Validation (No mention)
        2. Change Management (No mention)
        3. Product Complaint (Underestimate)
        4. Perform quality assurance (QA) and release of manufactured PET drugs (Underestimate)
        5. Create equipment and facility related procedures (Underestimate – includes no mention of the equipment and facility assessment and qualification activities that support the creation of said procedures).
        6. Creation of component specification sheet (underestimate – many firms produce multiple products requiring additional component specifications) is underestimate by 50%.
        7. Out of specification events average is underestimated.

8. Third-part disclosure burden is underestimated with respect to the number of Field Alert Reports submitted. In addition to initial FARs there are also follow-up and final FARs which are submitted for each event.
9. For all paperwork (SOPs, etc.) cited in this document there is no consideration for the significant amount of training that has to take place for all this documentation (creation, deployment and capturing training records).

b. Annual burden - Insufficient time for investigation taken into account (e.g., retesting may be required). The total number of batches release for corporate entities is significantly underestimated. Regulations are silent on the burden for Annual Product Review (APR). Due to the Covid-19 Pandemic the utilization of 704/706 Records Requests was heavily utilized by FDA. There is not accounting for the annual burden associated with these records requests.

3. Ways to enhance the quality, utility and clarity of the info to be collected - **APR is not specified in this docket. Time for APR collection/review is not discussed and is inconsistent with expectations of Investigators, as well as the review and approval of any investigation.**

4. Ways to minimize the burden of the collection - **Clarify as to whether APR is or is not required for PET. If APR is required, it needs to be clarified in these metrics.**

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 Sue Bunning at 703-340-4100 or by email at sbunning@medicalimaging.org.

Thank you for your consideration.

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.