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Division of Dockets Management (HFA – 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket No. FDA-2008-D-0525**

Dear Sir/Madam:

The following documents which are attached for your review represent the written comments of the Medical Imaging & Technology Alliance (MITA) on Docket No. FDA-2008-D-0525, “*Draft Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products*”:

- Letter with general comments on the draft guidance set forth below
- Draft guidance document with numbered lines in the text
- Letter with detailed comments on specific sections of the draft guidance, corresponding to the numbered lines in the text of the draft guidance

The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the collective voice of medical imaging equipment 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:

- Medical X-ray equipment
- Computed tomography (CT) scanners
- Ultrasound
- Nuclear imaging
- Radiation therapy equipment
- Magnetic resonance imaging (MRI)
- Imaging information systems

## General Comments

MITA appreciates the opportunity to share its views and concerns on the draft guidance. While MITA recognizes the efforts of FDA in developing this draft guidance, the document is deficient in a number of important respects.

In the Scope of the draft guidance, it is stated,

“As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, FDA agreed to develop guidance for use of medical imaging devices with “contrast agents or radiopharmaceuticals.”

Specifically, item I.N of the commitment letter states: *“FDA will, after consultation with affected parties, develop a guidance document intended to ensure timely and effective review of, and consistent and appropriate postmarket regulation and labeling recommendations for, diagnostic imaging devices used with imaging contrast agents and/or radiopharmaceuticals approved for the same or different indications.”*

In the INTRODUCTION to the draft guidance, FDA acknowledges that the document does not address specific scientific or technical content that should be provided in a regulatory submission to demonstrate the safety and effectiveness of an imaging product(s) for specific indications. Further, in the SCOPE of the draft guidance, FDA states that information pertaining to regulatory submissions for each specific indication would necessitate a separate guidance, and thus is beyond the scope of this document.

MITA believes that the current draft guidance is flawed in that it constitutes simply a general statement of policy approaches, rather than a guidance document designed to help ensure timely and efficient review of product submissions. The absence of “specific scientific or technical content” in the draft guidance very significantly reduces its utility to manufacturers seeking development of submissions for FDA review, and thus fails to meet FDA’s statutory commitment.

Based on the above, manufacturers would need to await the development of separate guidances for each indication for use. This would seriously undermine FDA’s commitment as mandated by MDUFA to produce a guidance document that would “ensure timely and effective review” of product submissions. The time and resources that would be required to develop separate guidances for each indication would be very substantial, and would be inefficient and wasteful of FDA and manufacturer resources.

Further, the draft guidance needs to provide an annotated flowchart as an aid to navigating the overall decision process. The flowchart should address all decisions used to determine the type of submission for the imaging device and/or agent and include guidance on suggested content for the submission. Typical decisions should clarify when the labeling of the device or imaging agent needs to be revised and when the level of specificity alters the legally marketed indication for use.

Given the numerous clinical indications in which imaging devices may be currently used with contrast agents, and the likelihood of the introduction of new clinical indications for contrast imaging, development of separate guidances for each indication would create an utterly unworkable regulatory process, contradict “least burdensome” principles, and would greatly impede, rather than facilitate, bringing the benefits of innovative contrast imaging technologies to patients.

MITA believes that FDA can and should meet its statutory commitment to provide effective guidance to manufacturers, by development of a comprehensive, detailed document that is applicable to a wide variety of clinical indications, rather than expending inordinate time and resources in developing a proliferation of specific guidance documents.

As noted above, our specific comments on the draft guidance are contained in the attached letter.

Consistent with these comments, MITA wants to encourage FDA to hold a public workshop to discuss the draft guidance and obtain wider stakeholder comment. Since the guidance affects both drug and device development, and the drug and device industries bring sometimes differing experience and perspectives, a public workshop would help ensure clarity of views and provide better confidence that the final guidance will provide the kind of roadmap envisioned by the MDUFA performance goal. MITA is willing to explore the feasibility of joining with other stakeholder groups to co-sponsor such a workshop.

Once again, we appreciate the opportunity to comment on the draft guidance. If you have any questions or need further information, please feel free to contact Richard Eaton of my staff at (703) 841-3248 or by e-mail at [reaton@medicalimaging.org](mailto:reaton@medicalimaging.org).

MITA stands ready to work with you and other interested stakeholders in addressing the critical regulatory issues on the use of imaging devices with contrast agents.

Sincerely,



Ilyse Schuman  
Vice President, National Electrical Manufacturers Association (NEMA)  
Managing Director, Medical Imaging & Technology Alliance (MITA)

Attachments