



Setting Standards for Excellence
1926 - 2001

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

July 28, 2004

5111 6. 13 -2 10:33

RE: Docket No. 2004-N-0181

Dear Sir/Madame:

This letter comes in response to the request by FDA, as set forth in the Federal Register Notice, 69 FR 21839, April 22, 2004, for the identification of the most pressing and/or technical hurdles causing major delays and other problems in the drug, device and/or biologic development process, as well as proposed approaches for solutions to these problems.

The National Electrical Manufacturers Association (NEMA) is the largest U.S. trade association representing the U.S. electroindustry. The Diagnostic Imaging and Therapy Systems Division represents over 90% of the market for x-ray imaging, CT, radiation therapy, magnetic resonance, nuclear medicine imaging, diagnostic ultrasound and medical imaging informatics equipment.

On March 16, 2004, FDA released a report entitled *Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products*. In this report, FDA has recognized that there are significant hurdles which exist in the product development process which have a crucial impact on the pace at which technological discoveries can be translated into development of medical products. The report describes ways in which the product development process, the "critical path," could be modernized to make the product development process more predictable with less cost.

NEMA wishes to commend FDA in acknowledging the importance of the product development process as a critical variable in terms of the speed at which these discoveries can be brought to market. We are encouraged that FDA is seeking the input of stakeholders to help identify and prioritize the most critical medical product development problems, and those areas which should be explored for potential solutions.

As set forth above, NEMA manufacturers produce a broad array of diagnostic imaging and therapeutic equipment, and are thus critical stakeholders in the product development process. Product design and validation procedures, among others, play a critical role in the product development process. One of the most problematic areas for medical imaging device manufacturers is the lack of an efficient regulatory pathway for use of magnetic resonance and diagnostic ultrasound devices with contrast agents.

National Electrical
Manufacturers Association
www.nema.org

1300 North 17th Street, Suite 1847
Rosslyn, VA 22209
(703) 841-3200
FAX (703) 841-5900

2004N-0181

C21

The absence of a clear and straightforward pathway in this area has created serious impediments in the product development process for bringing these important technologies to market for the benefit of patients. We look forward to sharing our views on this vital issue with you in greater detail in the future.

NEMA will be holding a meeting in August to discuss the FDA Critical Path Initiative. We intend in the next few months to provide our views to you on identifying both critical path hurdles and potential solutions for review and discussion.

Although the initial deadline for comments will expire on July 30, 2004, we understand that the July date is simply the concluding date for the first iteration of comments, and that stakeholders will have ample opportunities subsequent to this date to provide their views to you once a mechanism has been established by FDA. NEMA wishes to express its interest in providing input and opening up an ongoing discussion with you on these issues as the process unfolds in the coming months.

Please do not hesitate to contact me if you have any further questions. I can be reached at (703) 841 – 3248.

NEMA stands ready to work with you to enhance the efficiency of the product development process in order to bring the benefits of safe and effective medical technologies to the public. We look forward to beginning our dialogue with you in the near future.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard M. Eaton". The signature is fluid and cursive, with a large initial "R" and "E".

Richard M. Eaton,
Industry Manager