



Setting Standards for Excellence

ROBERT G. BRITAIN
Vice President, Medical Products

8 3 6 3 '00 MAR 23 P2:18
March 20, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Reference: Docket No. 99N-4784, Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification: Proposed rule.

This letter represents the comments of the National Electrical Manufacturers Association (NEMA) to the announcement in the Federal Register, 21 CFR Part 807, Proposed rule: "Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification." NEMA appreciates the opportunity to provide its comments on the proposed rule.

NEMA, the National Electrical Manufacturers Association, is the leading U.S. trade association representing and serving America's electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than 95% of U.S. manufacturers of x-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance, nuclear medicine imaging and medical informatics equipment.

NEMA believes this proposal does not address public health concerns, but rather is a mechanism to facilitate the disposition of FOI requests for FDA. The current 510(K) summary provides the information most users would need to make informed decisions and provides information most patients may need about a medical device. If any further information is required, then detailed information is available through the existing FOI process. It appears this rule is more of a mechanism by which FDA will regulate legitimate business practice and enforce subrogation of its own responsibilities rather than regulate the safety of medical devices. NEMA believes this proposal will only serve to add additional burden on manufacturers.

Currently, FDA and, subsequently, companies receive few FOI requests in a year. NEMA member companies have received FOI requests for only 18% of the total number of 510(K)s submitted to FDA in the last 4 years. Most products never have an FOI request, some products get multiple FOI requests and some requests are erroneous and need never be processed. FOI presumes an "as required" specified need, not an indiscriminate availability. The proposed rule will impose additional burdens on manufacturers because it will force industry to provide material

National Electrical
Manufacturers Association

1300 North 17th Street, Suite 1847
Rosslyn, VA 22209
(703) 841-3241
FAX (703) 841-3341
bob_britain@nema.org

99N-4784

CR

without a demonstrated need. Industry does not understand FDA's current need to expedite FOI releases given the low frequency of FOI requests and the availability of 510(K) summaries. More information can be provided when specifically requested. Current practice meets the requirement of the regulation with a reasonable effort by industry and FDA. It should also be noted that the Paperwork Reduction Act and FDAMA have clear goals of minimizing the amount of paperwork required to meet FDA requirements.

FDA has not provided any data with regard to the number of hours or resources currently allocated to respond to the relatively few FOI requests versus the number of hours required to process approximately 5000 510(k)s a year for the Internet. FDA has not provided any factual data to support its proposal. In fact, the additional workload may well be more resource intensive than the present system. In a time of concerns about budgetary restrictions, NEMA wonders if FDA has evaluated the handling and storage costs associated with the additional submissions? Historically, requests for these have been infrequent. Existing FTE's would need to remain on staff to process those submissions currently on file without a redacted version - new staff would be required to handle the increased volume which would result from these proposed requirements. Manufacturers are also concerned about the possible multiple redactions if second requests are made because an already redacted 510(k) has been lost.

Another concern we have is that the proposed rule does not give manufacturers the ability to review the ODE reviewer's notes regarding the submission. Manufacturers traditionally have been able to review them prior to submitting redacted 510(k)s. These often very revealing notes, made as part of the review and included with the 510(k), are available through FOI and often contain confidential technical information that would not get redacted by the manufacturer in the proposed procedure. If FDA is really interested in making sure that the person with the best ability to redact the submission performs the activity, then the manufacturer should be given these notes to redact upon receipt of the SE decision.

Protection of copyrighted material is also a concern. One of FDA's proposals will force a copyright holder to sign away its rights in order to have a 510(k) cleared. Although FDA indicates that copyrights will be protected, it appears that FDA will disseminate copyrighted material without any monitoring of the use or dissemination of that material by the FOI requestor, and there is no proposed method to prevent duplication of copyrighted material. Preventing inclusion of copyrighted material in a 510(k) could seriously compromise the quality of submissions.

FDA proposes to add the redaction proposal to their Compliance armamentarium. In spite of the lack of any statutory support for this proposal, FDA wishes to be able to fine firms \$15,000 per failure to provide the information. FDA also wishes to be the sole authority to make the determination whether or not a firm is in compliance. FDA is clearly making a tremendous leap from a voluntary productivity enhancement request to an enforceable violation. The agency has even suggested that "some of the resources currently devoted to identifying what information should be protected from disclosure could be redirected ... to compliance actions against submitters who do not follow the new rule." Thus, it is considering reducing its FOI productivity in order to take additional and unnecessary compliance actions. How does this rationale benefit industry or individuals requesting information?

Finally, the majority of NEMA members see no need to speed the FOI process and are not prepared or willing to accept FDA's responsibility as their own. FDA's proposal clearly seeks to cost defer legitimate FDA activities to industry. The proposed regulation is not cost justified and has no statutory basis. It is not FDA's role to regulate legitimate business practice, but to regulate medical devices for the sake of the public's health.

NEMA appreciates the opportunity to comment on FDA's proposed Requirement for Redacted Version of Substantially-Equivalent Premarket Notification and encourages the agency to seriously consider the industry concerns presented in this comment letter.

If you have any questions about these comments or if NEMA may be of assistance, please contact me at 703-841-3241 or bob_britain@nema.org.

Sincerely yours,

A handwritten signature in black ink that reads "Robert G. Britain". The signature is written in a cursive style with a large, stylized initial "R".

Robert G. Britain
Vice President
Medical Products



Setting Standards for Excellence

ROBERT G. BRITAIN

Vice President, Medical Products

March 20, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Reference: Docket No. 99N-4784, Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification: Proposed rule.

This letter represents the comments of the National Electrical Manufacturers Association (NEMA) to the announcement in the Federal Register, 21 CFR Part 807, Proposed rule: "Premarket Notification; Requirement for Redacted Version of Substantially-Equivalent Premarket Notification." NEMA appreciates the opportunity to provide its comments on the proposed rule.

NEMA, the National Electrical Manufacturers Association, is the leading U.S. trade association representing and serving America's electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents more than 95% of U.S. manufacturers of x-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance, nuclear medicine imaging and medical informatics equipment.

NEMA believes this proposal does not address public health concerns, but rather is a mechanism to facilitate the disposition of FOI requests for FDA. The current 510(K) summary provides the information most users would need to make informed decisions and provides information most patients may need about a medical device. If any further information is required, then detailed information is available through the existing FOI process. It appears this rule is more of a mechanism by which FDA will regulate legitimate business practice and enforce subrogation of its own responsibilities rather than regulate the safety of medical devices. NEMA believes this proposal will only serve to add additional burden on manufacturers.

Currently, FDA and, subsequently, companies receive few FOI requests in a year. NEMA member companies have received FOI requests for only 18% of the total number of 510(K)s submitted to FDA in the last 4 years. Most products never have an FOI request, some products get multiple FOI requests and some requests are erroneous and need never be processed. FOI presumes an "as required" specified need, not an indiscriminate availability. The proposed rule will impose additional burdens on manufacturers because it will force industry to provide material

National Electrical
Manufacturers Association

1300 North 17th Street, Suite 1847
Rosslyn, VA 22209
(703) 841-3241
FAX (703) 841-3341
bob_britain@nema.org

without a demonstrated need. Industry does not understand FDA's current need to expedite FOI releases given the low frequency of FOI requests and the availability of 510(K) summaries. More information can be provided when specifically requested. Current practice meets the requirement of the regulation with a reasonable effort by industry and FDA. It should also be noted that the Paperwork Reduction Act and FDAMA have clear goals of minimizing the amount of paperwork required to meet FDA requirements.

FDA has not provided any data with regard to the number of hours or resources currently allocated to respond to the relatively few FOI requests versus the number of hours required to process approximately 5000 510(k)s a year for the Internet. FDA has not provided any factual data to support its proposal. In fact, the additional workload may well be more resource intensive than the present system. In a time of concerns about budgetary restrictions, NEMA wonders if FDA has evaluated the handling and storage costs associated with the additional submissions? Historically, requests for these have been infrequent. Existing FTE's would need to remain on staff to process those submissions currently on file without a redacted version - new staff would be required to handle the increased volume which would result from these proposed requirements. Manufacturers are also concerned about the possible multiple redactions if second requests are made because an already redacted 510(k) has been lost.

Another concern we have is that the proposed rule does not give manufacturers the ability to review the ODE reviewer's notes regarding the submission. Manufacturers traditionally have been able to review them prior to submitting redacted 510(k)s. These often very revealing notes, made as part of the review and included with the 510(k), are available through FOI and often contain confidential technical information that would not get redacted by the manufacturer in the proposed procedure. If FDA is really interested in making sure that the person with the best ability to redact the submission performs the activity, then the manufacturer should be given these notes to redact upon receipt of the SE decision.

Protection of copyrighted material is also a concern. One of FDA's proposals will force a copyright holder to sign away its rights in order to have a 510(k) cleared. Although FDA indicates that copyrights will be protected, it appears that FDA will disseminate copyrighted material without any monitoring of the use or dissemination of that material by the FOI requestor, and there is no proposed method to prevent duplication of copyrighted material. Preventing inclusion of copyrighted material in a 510(k) could seriously compromise the quality of submissions.

FDA proposes to add the redaction proposal to their Compliance armamentarium. In spite of the lack of any statutory support for this proposal, FDA wishes to be able to fine firms \$15,000 per failure to provide the information. FDA also wishes to be the sole authority to make the determination whether or not a firm is in compliance. FDA is clearly making a tremendous leap from a voluntary productivity enhancement request to an enforceable violation. The agency has even suggested that "some of the resources currently devoted to identifying what information should be protected from disclosure could be redirected ... to compliance actions against submitters who do not follow the new rule." Thus, it is considering reducing its FOI productivity in order to take additional and unnecessary compliance actions. How does this rationale benefit industry or individuals requesting information?

Finally, the majority of NEMA members see no need to speed the FOI process and are not prepared or willing to accept FDA's responsibility as their own. FDA's proposal clearly seeks to cost defer legitimate FDA activities to industry. The proposed regulation is not cost justified and has no statutory basis. It is not FDA's role to regulate legitimate business practice, but to regulate medical devices for the sake of the public's health.

NEMA appreciates the opportunity to comment on FDA's proposed Requirement for Redacted Version of Substantially-Equivalent Premarket Notification and encourages the agency to seriously consider the industry concerns presented in this comment letter.

If you have any questions about these comments or if NEMA may be of assistance, please contact me at 703-841-3241 or bob_britain@nema.org.

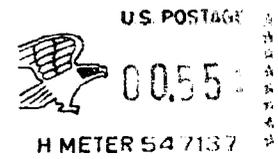
Sincerely yours,

A handwritten signature in black ink that reads "Robert G. Britain". The signature is written in a cursive, flowing style.

Robert G. Britain
Vice President
Medical Products



300 N. 17th Street • Suite 1847
Rosslyn, VA 22209



Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.