



Setting Standards for Excellence

Robert G. Britain

Vice President, Medical Products

August 17, 2004

Food and Drug Administration
Division of Documents Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0194

Dear Sir/Madame:

This letter comes in response to your request for comments on the proposed rule published on May 7, 2004 in 69 Federal Register 25527, on "Definition of Primary Mode of Action of a Combination Product", Docket No. 2004N-0194. NEMA would like to express its concerns that the proposed rule would thwart the purpose and intent of the Medical Device User Fees and Modernization Act of 2002 (MDUFMA).

The National Electrical Manufacturers Association (NEMA) is the largest U.S. trade association representing America's electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA 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. We appreciate the opportunity to share our views with you.

In MDUFMA, section 204 (4)(A), the Office of Combination Products (OCP) was established to ensure the prompt assignment of combination products to agency centers and the timely and effective premarket review of these products. Congress recognized that with the growing emergence of combination products, achieving timely and effective premarket review of these products would become increasingly more difficult and complex, and thus deemed it important that a mechanism be created to streamline and enhance the efficiency of premarket review of these innovative technologies. Further, in section 204 (4) (B), the OCP was charged with the responsibility, with respect to each combination product, to promptly assign an agency center with primary jurisdiction for the premarket review of that product. Once such assignment

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was made, the OCP would be required in section 204 (C) (i) to ensure timely and effective premarket review by overseeing the timeliness of reviews and coordinating reviews when more than one center was involved.

Inherent in the function of the OCP in assignment of combination products to the appropriate FDA centers is the responsibility of OCP to determine the “primary mode of action” (PMOA) of the combination product.

The proposed rule seeks to define “primary mode of action” as “the single mode of action of a combination product that provides the most important therapeutic action of the combination product. “For the purposes of PMOA, “therapeutic effect” or action includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body.” This would be the mode of action which is expected to make the greatest contribution to the overall therapeutic effects of the combination product. We are concerned that the proposed rule however does not provide a method on how “the most important therapeutic action” or “the greatest contribution to the overall therapeutic effects” is to be determined.

Moreover, it was the intent of Congress to confer authority and responsibility on the OCP to direct and manage the assignment process for combination products. However, the proposed rule, with its creation of an algorithm for determination of the appropriate Center to assign a combination product, would, if adopted, violate the intent of Congress expressed in MDUFMA by introducing two criteria for assignment of a combination product which were not included within the statute when it was enacted. Specifically, when OCP cannot determine the primary mode of action, the proposed rule would invoke the following criteria:

1. Assignment of the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with respect to the combination product as a whole

If no other combination products exist which present similar questions of safety and effectiveness with respect to the combination product as a whole, then the second criterion is to be applied, specifically,

2. Assignment of the combination product to the agency component with the most expertise to evaluate the most significant safety and effectiveness questions presented by the combination product

Neither of these criteria were included in MDUFMA for determining the combination product assignment process when it was enacted. Also, importantly, no method was provided in the proposed rule on how the agency was to define “similar questions of safety and effectiveness” or the “most significant safety and effectiveness questions.”

It should be noted that if FDA were not able to decide the PMOA determination on a combination product, it is doubtful whether it would be able to determine which Center had the –

best expertise or which Center regulated other combination products that presented similar questions of safety and effectiveness.

The purpose of MDUFMA was to create a new office as a departure from past practices at FDA with regard to assignment of combination products to appropriate Centers. However, implementation of the criteria set forth in the proposed rule into the process for assignment of combination products to the appropriate Centers would contradict the purpose of MDUFMA, and instead allow OCP to avoid deciding difficult PMOA issues, and thus invite the Office to circumvent the requirements of MDUFMA and revert to past FDA practices.

Since the effect of the proposed rule would be to rely upon past regulatory practices at the FDA regarding combination products, instead of focusing upon the actual technological characteristics of the combination product, significant delays could occur in the process of assignment of combination products to appropriate Centers at FDA. Greater conflict between the Centers could also arise which would further slow the product review process at the agency. This would directly contradict the express purpose of MDUFMA to achieve effective and timely review of combination products.

Since NEMA believes that adoption of the proposed rule would thwart the intent of Congress in enactment of MDUFMA, we urge the FDA to withdraw the proposed rule and thus permit the combination product assignment process to work as intended by the statute. This will enable progress to continue to be made in reducing regulatory obstacles to the product approval process, and thus allow the benefits of innovative medical technologies to be made available to patients more rapidly.

If you have any questions, or need additional information, please feel free to contact me at (703) 841 – 3241.

Again, we appreciate the opportunity to share our views with you. NEMA stands ready to work with you in advancing the quality of healthcare for patients.

Sincerely,

A handwritten signature in cursive script that reads "Robert G. Britain". The signature is written in black ink and is positioned below the typed name "Robert G. Britain".