



A Coalition of 11 Medical Societies Representing  
200,000 Specialty Physicians in the United States

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April 27, 2007

Andrew C. von Eschenbach, M.D.  
FDA Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration (FDA)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Dear Dr. von Eschenbach:

Founded in 2001, the Alliance of Specialty Medicine (Alliance) represents over 200,000 physicians in 11 medical specialty organizations and serves as a strong voice for specialty medicine. The Alliance is comprised of organizations that represent non-surgical and surgical specialties, as well as hospital and office-based physicians. The Alliance appreciates the opportunity to comment on the Medical Device User Fee Act (MDUFMA) II [Docket 2007N-0068].

The undersigned members of the Alliance of Specialty Medicine are united in support of a well-resourced FDA. In particular, we advocate for a sound financial base for the Center for Devices and Radiological Health (CDRH) and the Center for Biological Evaluation and Research (CBER) to ensure the safety of medical devices through review, approval, and post-market activities. An adequately capitalized medical device program is essential for bringing safe and effective medical devices to patients expeditiously.

Therefore, as Congress considers revisions to the Medicare Device User Fee Act as part of MDUFMA II negotiations, the Alliance supports a policy that ensures adequate resources for the aforementioned activities. The user fee program is one method of providing additional resources to improve timely review that is intended to ensure that safe and effective products are brought to market quickly for patients.

### **New User Fees**

The Alliance is encouraged by the development of a new user fees program that would generate approximately fifty percent of the total fee revenues. As negotiated by the agency and device manufacturers, new fees for manufacturer registration and annual report filing will provide a more stable method for the FDA to collect the necessary resources than under MDUFMA I. The Alliance also applauds the continued lower fees for small businesses in the MDUFMA II proposal. Overall, this proposed new user-fee structure will add more stability to the program rather than the top heavy structure of the fees assessed to the pre-market products under MDUFMA I. Ultimately a more streamlined and financially sufficient structure is beneficial to patients, who will be the recipients of new medical devices and biologics.

### **Guidance Document Development**

The Alliance acknowledges the success of the utilization and development of FDA guidance documents. These documents assist in predictability and transparency for manufacturers in the development of pre-market device and pre-market notification submissions, as well as expediting the review process. Manufacturers often cite

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American Academy of Dermatology Association • American Association of Neurological Surgeons • American Association of Orthopaedic Surgeons  
American College of Emergency Physicians • American College of Obstetricians and Gynecologists  
American Gastroenterological Association • American Society for Therapeutic Radiology and Oncology  
American Society of Cataract & Refractive Surgery • American Urological Association • Congress of Neurological Surgeons  
National Association of Spine Specialists

receiving different interpretations of product reviews. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as a special control document to support a downclassification, thereby reducing the FDA resources spent on pre-market product reviews.

However, an unintended consequence of the FDA's efforts to meet performance goals in MDUFMA I was the development of only a few guidance documents. The American Association of Orthopaedic Surgeons submitted a guidance document to a FDA docket over three years ago, and a draft guidance has yet to be published. While the FDA acknowledges differing guidance document priorities within the divisions, offices, and centers, the agency must define a better pathway to guarantee the development of needed guidance documents in a timely manner.

Furthermore, the Alliance strongly encourages the FDA to streamline its internal legal processes with regard to reviewing guidance documents. While it is important to provide a solid legal foundation for regulatory actions, the FDA has become encumbered in its legal review of documents. Internal processes should be made more efficient to ensure thorough but swift review by the Chief Counsel; at present, delays prevent patients' access to safe and effective medical devices. The Alliance stands ready to assist the FDA in revising and creating guidance documents to address critically important clinical information.

### **Cycle Goals**

Further, the Alliance supports the elimination of interim cycle goals and urges the agency to interact informally with submission applicants prior to sending deficiency and not approvable letters. The application of performance goals for final decisions is necessary and appropriate, however.

Again, the Alliance appreciates the opportunity to comment on MDUFMA II. We encourage you to contact Jeanie Kennedy ([jkennedy@aaos.org](mailto:jkennedy@aaos.org) or 202/546-4430) or Laura Saul Edwards ([ledwards@aad.org](mailto:ledwards@aad.org) or 202/842-3555) the co-chairs of the Alliance's Drugs and Devices Work Groups with any specialty medicine specific issues.

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Sincerely,

American Academy of Dermatology Association  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Emergency Physicians  
American College of Obstetricians and Gynecologists  
American Gastroenterological Association  
American Society for Therapeutic Radiology and Oncology  
American Society of Cataract & Refractive Surgery  
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