



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

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October 14, 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

RE: Docket Number 2007D-0201

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the proposed guidance "Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents" as published in the Federal Register on July 19, 2007 [Docket No. 2007D-0201]. The AAOS appreciates the efforts of the Food and Drug Administration to clarify a regulatory pathway for these types of devices.

#### **Guidance Document Development**

The Academy thanks the FDA for the development and dissemination of this guidance document. The AAOS has commented repeatedly over the last few years on the lack of published guidance documents following the creation of the Medical Device User Fee Act (MDUFMA) of 2002 performance goals. The MDUFMA performance goals demanded progressively challenging timelines for the review of pre-market approval applications, biological license applications, and 510(k) submissions. Prior to the passage of MDUFMA 2002, the timelines for performance were more discretionary. In order to meet the performance goal timelines, priorities were shifted with fewer resources devoted to guidance document development. Thus, the diminished production of the Center for Devices and Radiological Health (CDRH) guidance documents was an unintended consequence of the MDUFMA of 2002.

The AAOS is encouraged that the structure of the 2007 device user fees and review goals in the Food and Drug Administration Amendments Act of 2007 (FDAAA) provide for more stable operating procedures. The new fee structure and performance goals should provide additional FDA resources for guidance document development.

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The Academy 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 notification submissions as well as expediting the review process. Manufacturers often cite receiving different interpretations of product reviews. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as special control documents to support a downclassification. The AAOS stands ready to assist the FDA in revising and creating guidance documents to address critically important, clinical information.

Therefore, the Academy is pleased that this guidance document was published for review and comment. The document has been developed with thoughtful consideration and the AAOS finds much of it to be reasonable and clinically relevant. We thank you for your efforts towards transparency and collaboration with interested stakeholders.

### **Concern for Antimicrobial Resistance**

The AAOS shares the FDA's concern that the addition of antimicrobial agents to medical devices may increase the risk of antimicrobial resistance. In March 2007 the Association for Professionals in Infection Control and Epidemiology, Inc. released findings of their national Methicillin-resistant *Staphylococcus aureus* (MRSA) prevalence study.<sup>1</sup> The study found a rate of MRSA that was 8-11 times higher than previous estimates. This data, coupled with the concerns expressed by the Infectious Disease Society of America's 2004 white paper "Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates... A Public Health Crisis Brews,"<sup>2</sup> underscores the need for caution where the use of antimicrobial agents is involved. The Academy has long advocated for the safe, responsible use of antimicrobials through its advisory statements *The Use of Prophylactic Antibiotics in Orthopaedic Medicine and the Emergence of Vancomycin-Resistant Bacteria*<sup>3</sup> and

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<sup>1</sup> Association for Professionals in Infection Control and Epidemiology, Methicillin Resistant *Staphylococcus aureus* (MRSA) Study Results, March 2007.  
[http://www.apic.org/Content/NavigationMenu/ResearchFoundation/NationalMRSAPrevalenceStudy/MRSA\\_Study\\_Results.htm](http://www.apic.org/Content/NavigationMenu/ResearchFoundation/NationalMRSAPrevalenceStudy/MRSA_Study_Results.htm)

<sup>2</sup> Infectious Disease Society of America, Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates... A Public Health Crisis Brews, 2004.  
<http://www.idsociety.org/WorkArea/showcontent.aspx?id=5554>

<sup>3</sup> American Academy of Orthopaedic Surgeons, *The Use of Prophylactic Antibiotics in Orthopaedic Medicine and the Emergence of Vancomycin-Resistant Bacteria*, February 2002.  
<http://www.aaos.org/about/papers/advistmt/1016.asp>

*Recommendations for the Use of Intravenous Antibiotic Prophylaxis in Primary Total Joint Arthroplasty.*<sup>4</sup> The AAOS believes the labeling recommendations outlined in the draft guidance will assist end users in making informed, responsible decisions about devices that include antimicrobial agents.

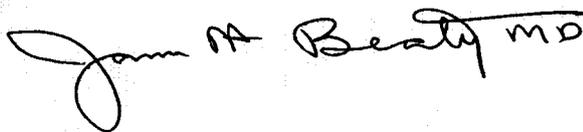
### **Risk/Benefit Assessment**

As cited in the proposed guidance, the risks and benefits of a device are evaluated as a part of the process of determining the device's safety and effectiveness. The Academy appreciates the FDA's efforts to bring safe, effective devices to market and is pleased that the activity spectrum, release kinetics, minimum effective concentration, mechanism of action, and toxicity of an antimicrobial agent included in a device will be considered as part of the overall assessment of substantial equivalency for modified devices.

### **Conclusion**

The AAOS appreciates the opportunity comment on this proposed guidance. We look forward to working with the FDA on efforts to ensure that safe and effective medical products reach patients more quickly.

Sincerely,

A handwritten signature in black ink that reads "James H. Beaty MD". The signature is written in a cursive style with a large, sweeping initial "J".

James H. Beaty, MD  
President, American Academy of Orthopaedic Surgeons

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<sup>4</sup> American Academy of Orthopaedic Surgeons, Recommendations for the Use of Intravenous Antibiotic Prophylaxis in Primary Total Joint Arthroplasty, June 2004.  
<http://www.aaos.org/about/papers/advistmt/1027.asp>