AAOS
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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:

The American Association of Orthopaedic Surgeons (AAOS/Association), representing over 17,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the Food and Drug Administration's Medical Device User Fee Act (MDUFMA) II [Docket 2007N-0068].

The AAOS is in support of a well-resourced FDA, in terms of MDUFMA II, specifically the Center for Devices and Radiological Health (CDRH) and the Center for Biological Evaluation and Research (CBER). An adequately capitalized medical device program is essential for bringing safe and effective medical devices to patients expeditiously.

Need for Increased Appropriations

The Association urges Congress and the Administration to substantively increase FDA appropriations over FY 2007. The agency is chronically under-funded compared to other federal health agencies while one quarter of consumer spending is expended on products under the purview of the FDA. The AAOS recommends increased appropriations every year that a new initiative is added to the agency's workload. This process should help ensure a well funded agency with adequate resources. If more work is added to the agency's docket without an increase in resources, the net effect will be an under-capitalized agency. Furthermore, an over reliance on user fees from industry is not beneficial for consumer confidence in the agency.

User Fee Program

The user fee program is therefore an adjunctive method for providing resources to the agency. These fees will improve timely medical product reviews and ensure that safe and effective therapies are brought to market quickly and will assist in ensuring a sound financial base for the agency.

New User Fees

The AAOS supports the development of new user fees to generate approximately fifty percent of the total fee revenues. New fees for manufacturer registration and annual fees assessed for filing reports will provide a more stable methodology for the FDA to collect necessary resources than under MDUFMA I. Additionally, fees for a request for product classification and 30-day notices should not prove to be too burdensome to industry. The Association applauds the continued lower fees for small businesses. Overall, this user-fee structure will add more stability to the program rather than the top heavy structure of significant fees assessed to pre-market products under MDUFMA I.

Guidance Document Development

The AAOS 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 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. Once a reclassification is accomplished, significant FDA resources previously spent on pre-market reviews can be shifted to other priority projects.

An unintended consequence of the FDA's efforts to meet performance goals in MDUFMA I was the development of few guidance documents. The AAOS submitted a draft document on the *Clinical Trial Design for Hip Replacement Systems* on January 29, 2004. Additionally, AAOS entered the *Proposed Guidance Document for Pre-clinical and Clinical Trial Design for Cervical and Lumbar Disc Replacement Systems* into a FDA docket on March 10, 2005. While we are encouraged to hear that the Division of General, Restorative, and Neurological Devices anticipates movement on these guidances in FY 2007, delays in publishing guidance documents is of significant concern to the AAOS. While the FDA acknowledges differing priorities within the divisions, offices, and centers, the agency must generate more resources or define another pathway for the development of needed guidance documents.

The Academy strongly encourages the FDA to streamline their internal processes. While it is important to provide a solid legal foundation for regulatory actions, the FDA has become encumbered in its review of guidance documents. The AAOS stands ready to assist the FDA in revising and creating guidance documents to address areas of critically important clinical information.

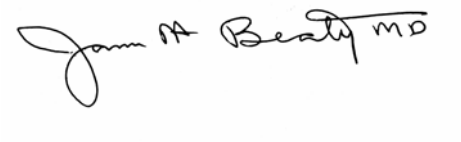
Cycle Goals

Further, the Academy supports the elimination of interim cycle goals to provide the agency with more opportunities to interact informally with sponsor prior to sending deficiency and not approvable letters. Moreover, the application of performance goals for final decisions is necessary and appropriate.

Again, the AAOS appreciates the opportunity to comment on MDUFMA II. Public and private sectors must work together to provide a safe environment for patients. The AAOS appreciates

the FDA's willingness to seek perspectives on the renewal of the user fee program. The Academy looks forward to working with the FDA on future efforts to bring safe and effective medical products to patients more quickly.

Sincerely,



James H. Beaty, MD

AAOS President