

Mark B. McClellan, M.D., Ph.D.
Food and Drug Administration
5630 Fishers Lane
Dockets Management Branch
HFA-305 Room 1061
Rockville, Maryland 20852

Docket No.: **03N-0077**

July 31, 2003

Dear Dr. McClellan:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board-certified orthopaedic surgeons, takes this opportunity to commend the FDA for its recognition and use of consensus standards in the premarket review and notification of medical devices. [Docket No. 03N-0077; Federal Register, April 28, 2003]

The Academy actively participates in standards development for medical devices and tissue-engineered medical products in both the American Society for Testing and Materials (ASTM) and the International Standards Organization (ISO). The AAOS supports the consensus model of standards development employed by these international standard-setting organizations. In the consensus model, all interested parties participate in the creation of the standard. The Academy maintains that the collaborative process of consensus-driven standards benefits the orthopaedic device community in that it facilitates communication between FDA, researchers, industry, and the clinical physician device users. This open dialogue provides a forum in which the orthopaedic community works in partnership to formulate technical standards of safety and efficacy that best serve the ultimate device users, our patients.

Again, the AAOS appreciates the FDA's inclusion of consensus-derived standards into their premarket review and notification processes. Thank you for this opportunity to express our support.

Sincerely,

James H. Herndon, MD
President