



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF  
ORTHOPAEDIC SURGEONS

April 8, 2015

Stephen Ostroff, MD  
Acting FDA Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

RE: Docket No. FDA-2014-N-1039

Dear Dr. Ostroff,

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) welcomes the opportunity to comment on the draft guidance "General Wellness: Policy for Low Risk Devices." AAOS champions the interests of patients by improving treatment options through education and research. We are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality orthopaedic care. AAOS is committed to keeping the world in motion through the prevention and treatment of musculoskeletal conditions.

AAOS appreciates the Agency's forward-thinking approach to emerging technologies, as reflected in this guidance. We recognize the challenge of maintaining a pace of guidance development to match that of innovators and the importance of monitoring evolving technology. Products that contribute to general wellness of patients are a welcome addition to the tools available for encouraging healthy lifestyles.

With respect to the latest generation of smart tools that interface with web-based applications to track various health measures, AAOS believes that consumers should be aware of the way in which this data may be stored and used. The public should also be apprised of the accuracy, or lack thereof, of these technologies, in order to support informed decision making. We are aware of standards development efforts by the Association for the Advancement of Medical Instrumentation (AAMI) to assist in the evaluation of these products. AAOS encourages the FDA to continue their established practice of collaborating with content experts by working with AAMI and similar groups.

AAOS thanks the FDA for considering our suggestions and hearing our concerns. We look forward to working with the FDA and other stakeholders to continue to advance the science of orthopaedic care and continuously improve patient safety and outcomes.

Sincerely,

David Teuscher, MD  
President, American Academy of Orthopaedic Surgeons