AAOS
American Association of Orthopaedic Surgeons

April 13, 2022

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Medical Devices; Quality System Regulation Amendments (Docket No. FDA-2021-N-0507)

Submitted electronically via regulations.gov

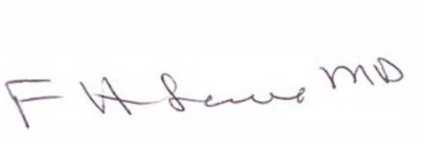
Dear Commissioner Califf:

On behalf of the 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we are pleased to share our position on the proposed rule, **Medical Devices; Quality System Regulation Amendments** (Docket No. FDA-2021-N-0507). In this rule, the Food and Drug Administration (FDA) proposes to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions set by the International Organization for Standardization (ISO) - ISO 13485:2016 Medical devices – *Quality management systems – Requirements for regulatory purposes*.

AAOS recognizes that safe and effective orthopaedic implants are central to high quality patient care. We also acknowledge that the testing and safety of orthopaedic implants is an international activity, with many vendors necessarily operating globally to simultaneously address multiple markets. As such, there should be consensus and harmony around testing and standards of implants, with efforts being led capably by standardization bodies such as ASTM International and the International Organization for Standardization (ISO). We support the agencies' efforts as they pertain to the standardization outlined in this proposed rule.

Thank you for your time and attention to the interests of the American Association of Orthopaedic Surgeons (AAOS) on the proposals made in Medical Devices; Quality System Regulation Amendments proposed rule. The AAOS looks forward to working closely with the FDA on further enhancing the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,



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