



AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

June 8, 2026

Takyiah Stevenson, PharmD
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 31, Rm. 2417
Silver Spring, MD 20993-0002

Dear Ms. Stevenson,

On behalf of the more than 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), thank you for the opportunity to comment to the Pharmacy Compounding Advisory Committee on Bulk Drug Substances Nominated for Inclusion on the Section 503A Bulk Drug Substances List.

The AAOS has carefully reviewed the available information regarding the clinical use of peptides. Clinicians in sports medicine are increasingly asked about these substances by patients and athletes, largely as a result of widespread marketing and public enthusiasm rather than robust scientific evidence. At present, there is very limited human clinical data to support the efficacy or safety of these products. Additional concerns include the lack of reliable information regarding purity, potency, and biological activity, particularly for peptides obtained through online or other non-FDA-regulated sources. While recent regulatory proposals aim to address some of these concerns by permitting compounding pharmacies to produce a limited number of peptides, the AAOS believes it is important to highlight the ongoing risks associated with their widespread use in the absence of adequate clinical evidence and regulatory oversight. The FDA, manufacturers and physicians all have a role to play in providing patients with complete and truthful information about their treatment and payment options.

Additionally, AAOS believes in the power of scientific innovation and the importance of bringing new treatments to patients. HHS should work to reduce regulatory barriers and burdens hampering the adoption of new technologies once they are proven to be safe and effective.

Thank you for this opportunity to comment. Should you wish to speak further, please contact Lori Shoaf, JD, MA, AAOS Office of Government Relations at shoaf@aaos.org.

Sincerely,

A handwritten signature in black ink that reads "Joel Mayerson MD, FAAOS".

Joel Mayerson, MD, FAAOS
AAOS Council on Advocacy Chair