U.S. FOOD & DRUG ADMINISTRATION

Khaled M. Mohamed
Director, Regulatory Affairs
Medexus Pharma, Inc.
29 N. Wacker Drive, Suite 704
Chicago, IL 60606

Feburary 13, 2023

Re: Docket No. FDA-2022-P-1104

Dear Mr. Mohamed:

This letter responds to your citizen petition received on June 9, 2022, requesting that the Food and Drug Administration (FDA) determine whether Aristospan (triamcinolone hexacetonide) injectable suspension, 20 milligrams (mg)/milliliter (mL), has been voluntarily withdrawn for reasons of safety or effectiveness.

Although your citizen petition requested only a determination regarding Aristospan (triamcinolone hexacetonide) injectable suspension, 20 mg/mL, for the sake of efficiency, FDA expanded the scope of the determination to also include Aristospan (triamcinolone hexacetonide) injectable suspension, 5 mg/mL. FDA has reviewed its records and determined that Aristospan (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Aristospan (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-4654.

Sincerely,

Diana J. Pomeranz
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov