U.S. FOOD & DRUG ADMINISTRATION

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

December 6, 2022

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

Dear Mr. Mohamed:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 9, 2022. Your petition requests that the Agency determine whether Aristospan (triamcinolone hexacetonide) injectable suspension, 20 mg/mL, has been voluntarily withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.12.06 14:28:00 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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