June 15, 2022

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

Sent via email to: khaled.mohamed@medexus.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug declare that a 2 mL fill volume for Triamcinolone hexacetonide injectable suspension, USP (20 mg/mL), is acceptable for submission as an Abbreviated New Drug Application (ANDA) and that the total vial content for this injectable suspension be increased from 1 mL to 2 mL; increasing the total strength per vial to 40 mg in support of an ANDA registration to address the current drug shortage was received and processed under CFR 10.30 & 10.35 by this office on 06/14/2022.

It was assigned docket number FDA-2022-P-1168. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S Digitally signed by Karen P. Malvin -S Date: 2022.06.16 08:12:40 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)