



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

December 11, 2015

Travis A. Leeah, RPh, MBA
Chief Executive Officer
Unique Pharmaceuticals, Ltd.
5920 S. General Bruce Drive
Temple, TX 76502

Dear Mr. Leeah:

We have completed our review of the Establishment Inspection Reports (EIR) for the inspections conducted at your facility located at 5920 S. General Bruce Drive, Temple, TX 76502 from, March 17, 2014 to April 2, 2014; June 9, 2014 – June 20, 2014; and January 13, 2015, to January 23, 2015, by the U.S. Food and Drug Administration (FDA). We acknowledge the corrective actions implemented by Unique Pharmaceuticals, Ltd. to address our concerns regarding's the lack of sterility assurance for sterile drug products produced by your firm. We further acknowledge your firm resumed production and distribution of sterile drug products on March 31, 2015. Future FDA inspections will evaluate the adequacy and sustainability of these corrections.

This letter is not intended as an endorsement or certification of your facility. It remains your responsibility to assure continued compliance with the requirements of section 503B of the Federal Food, Drug and Cosmetic Act, including current good manufacturing practices (CGMPs).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. Enclosed is a copy of the EIRs. The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. It is being provided to you for information purposes only and may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining additional information under FOIA.

If there is any question about the released information, please feel free to contact Jeff R. Wooley, Compliance Officer, 214-253-5251, or at 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204.

Sincerely,

for 
Reynaldo R. Rodriguez, Jr.
Dallas District Director

Enclosure: EIR