DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway Suite #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	01/10/2018-01/24/2018
	FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Arta Shaun Noorian, Founder and CEO

FIRM NAME	STREET ADDRESS
Empower Pharmacy	5980 West Sam Houston Parkway North Suite 300
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Houston, TX 77041	Outsourcing Facility

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation #1

There is a failure to thoroughly investigate any unexplained discrepancy or failure of a batch, regardless of whether the batch has been distributed, or a failure to expand an investigation to assess other batches that may also be impacted.

Specifically,

A review of your firm's endotoxin failure, occurring on 10/25/2017 for Lot No. 36029; Tri-Amino (L-Arginine HCL/L-Citrulline/L-Ornithine) 100/100/100 mg/mL, revealed that the investigation was incomplete in that:
1) Your firm failed to document a root-cause for the endotoxin failure.
2) Your firm did not implement any corrective actions or preventative measures to assure that future endotoxin failures will not occur when manufacturing this product.
3) Your firm did not evaluate whether other associated lots were impacted.

Review of your firm's potency failure, occurring on 10/16/2017 for Lot No. 35979; HCG Lyophilized 3000 IU/ vial, revealed that the investigation was incomplete in that:
1) Your firm failed to document a root-cause for the potency failure.
2) Your firm did not implement any corrective actions or preventative measures to assure that future potency failures will not occur when manufacturing this product.
3) Your firm did not evaluate whether other associated lots were impacted.

THIS IS A REPEAT OBSERVATION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Jason R. Caballero Sha'tina R. Alridge	Jason R. Caballero, CSO Sha'tina Alridge, CSO	01/24/2018