10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS **Warning Letter** 320-17-37

April 28, 2017

Mr. Tushar Patel
Managing Director
Vikshara Trading & Investments Ltd
Opp: Anup Engineering
Odhav Road
Ahmedabad 382415, Gujarat
India

Dear Mr. Patel:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Vikshara Trading & Investments Ltd at Opp: Anup Engineering, Odhav Road, Ahmedabad, Gujarat, on October 18, 2016.

Our investigator documented that your firm delayed and limited an FDA inspection. Under the FD&C Act, as amended by the Food and Drug Administration and Innovation Act (FDASIA), section 707, 21 U.S.C. 351(j), your drugs are adulterated in that they have been manufactured, processed, packed, or held in an establishment where the owner or operator has delayed and/or limited an inspection.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211. Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drugs are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your November 2, 2016, response in detail.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm delayed FDA's attempts to schedule a pre-announced inspection.

On April 25, 2016, FDA contacted your firm to facilitate the inspection process and ensure appropriate records and personnel would be available. On June 18, 2016, you notified FDA that "factory workers and staff have gone on strike." On June 20, 2016, you informed FDA that workers had blocked off the entrance of the facility as part of their protest. As a result of these communications FDA cancelled our pre-announced June 27, 2016, inspection.

On July 15, 2016, you informed FDA that your employees remained on strike. On August 8, 2016, you provided purported evidence of the strike, including copies of employee resignation letters and a photograph of striking employees blocking the entrance to your facility.

Despite your assertions that your employees were on strike, FDA obtained evidence that your firm actively manufactured numerous products, including at least **(b)(4)** batches of drugs, between July 11, 2016 and August 9, 2016.

Your false statements to FDA regarding the purported strike at your facility delayed FDA's scheduling and conducting of a pre-announced inspection.

2. Your firm limited FDA's inspection.

FDA entered your facility on October 18, 2016. Your firm's actions during this inspection significantly hindered FDA from fully assessing your compliance with CGMP. For example, doors to the **(b)(4)** vessel room and packaging and labeling storage areas were locked, impeding reasonable access for the investigator to these areas, and limiting this inspection.

3. Failure to provide records required to be readily available for authorized inspection (21 CFR 211.180(c)).

During the inspection on October 18, 2016, your firm did not provide batch records to our investigator. At the conclusion of the inspection, you stated that you would provide these records electronically within a matter of days. To date, FDA has not received any batch records.

Unkept Facility

During the inspection, the lights were off in the facility. In those areas that were physically accessible, our investigator had to perform parts of the walkthrough in the dark, using a flashlight. Even with limited visibility, our investigator observed **(b)(4)** powder scattered throughout the production areas, including powder caked on the floor. In addition, our investigator observed empty boxes, trash, finished drug products covered in powder, and containers littered throughout the facility.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

FDA placed your firm on Import Alert 66-40 on February 8, 2017, and on Import Alert 99-32 on February 9, 2017.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in FDA continuing to refuse admission of articles manufactured at Vikshara Trading & Investments Ltd at Opp: Anup Engineering, Odhav Road, Ahmedabad 382415, Gujarat into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion. Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov or mail your reply to:

Hien K. Lieu
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3004982352.

Sincerely,
/S/
Thomas J. Cosgrove
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research