WARNING LETTER

Shanghai Institute of Pharmaceutical Industry

MARCS-CMS 574821 — AUGUST 29, 2019

Delivery Method:
VIA UPS
Product:
Drugs

Recipient:
Ms. Hongjuan Pan
Testing Laboratory Director
Shanghai Institute of Pharmaceutical Industry
No. 285 Gebaini Road
Pudong Xinqu Shanghai Shi, 201203
China

Issuing Office:
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States

Warning Letter 320-19-40

August 29, 2019

Dear Ms. Pan:

The U.S. Food and Drug Administration (FDA) notified your site, Shanghai Institute of Pharmaceutical Industry at No. 285 Gebaini Road, Pudong District, Shanghai, of a planned surveillance and pre-approval inspection of your drug product testing facility from November 29 to December 4, 2018. Your firm refused the pre-announced inspection in a written response to the FDA China Office on December 4, 2018.

Your firm is listed as a contract testing laboratory that provides active pharmaceutical ingredient (API) characterization and/or identification testing to support multiple abbreviated new drug applications (ANDAs).

Under section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(j), drugs are deemed adulterated if they are manufactured, processed, packed, or held in an establishment and the owner, operator, or agent delays, denies, limits, or refuses an inspection.

See FDA's guidance document, *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection,* at https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm360484.pdf (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm360484.pdf).

Until FDA is permitted to inspect your facility and confirms compliance with current good manufacturing practice (CGMP), this office may recommend withholding approval of any new applications or supplements listing your firm as a drug manufacturer.

After you receive this letter, respond to this office in writing within 15 working days.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov) or mail your reply to:

Carrie Ann Plucinski

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 3002808132.

Sincerely,

/S/

Francis Godwin

Director

Office of Manufacturing Quality

Office of Compliance

Center for Drug Evaluation and Research

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)