WARNING LETTER

Mei Lan Thailand Co., Ltd.

MARCS-CMS 672783 — JANUARY 22, 2024

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mrs. Lan Pu

Managing Director

Mei Lan Thailand Co., Ltd.

35/252-253 Moo 2, Tambol Bangnamched, Muang District
Muang Samut Sakhon, Samut Sakhon 74000
Thailand

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

United States

Warning Letter 320-24-16

January 22, 2024

Dear Mrs. Lan Pu:

The U.S. Food and Drug Administration (FDA) notified your site, Mei Lan (Thailand) Co., Ltd., FEI 3012190301, at 35/252-253 Moo 2 , Tambol Bangnamched, Muang District, Muang Samut Sakhon, Samutsakorn, Thailand, of a planned inspection of your drug manufacturing facility from September 18 to 22, 2023.

Your firm is registered as an active pharmaceutical ingredient (API) manufacturer and manufactures crude **(b)(4)**.

On May 23, 2023, the FDA sent an electronic notice of inspection to the contact email address provided in your registration file. This request went unanswered, as did the second and third email requests sent on June 6 and 21, 2023, respectively. An FDA representative then attempted to contact your U.S. Agent on August 25, 2023. A fourth email attempt to contact you was sent on August 29, 2023, but you failed to respond. The Agency then sent a follow-up written request via UPS, that was delivered to the physical address provided in your registration file on August 29, 2023. Delivery to you was confirmed by the shipper, but you failed to respond.

Under section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(j), your drugs are adulterated in that they have been manufactured, processed, packed, or held in an establishment that delays, denies, or limits an inspection, or refuses to permit entry or 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.

FDA placed your firm on Import Alert 55-03 on January 18, 2024.

Until FDA is permitted to inspect your facility and confirms compliance with CGMP, we may withhold approval of any new applications or supplements listing your firm as a drug manufacturer. In addition, shipments of articles manufactured at Mei Lan (Thailand) Co., Ltd., at 35/252-253 Moo 2, Tambol Bangnamched, Muang District, Muang Samut Sakhon, Samutsakorn, Thailand into the United States that appear to be adulterated or misbranded are subject to being detained or refused admission pursuant to section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3).

After you receive this letter, respond to this office in writing within 15 working days. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices, and/or submit a request to schedule an FDA inspection.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3012190301 and ATTN: Rokhsana Jazi.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research