WARNING LETTER

Chengdu KeCheng Fine Chemicals Co., Ltd.

MARCS-CMS 659389 — JUNE 20, 2023

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Ye

General Manager

Chengdu KeCheng Fine Chemicals Co., Ltd.

Floor 9, No. 18 Chuangye Road
Chengdu High-Tech District
Chengdu Shi Sichuan Sheng, 610000
China

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Warning Letter 320-23-16

June 20, 2023

Dear Mr. Ye:

Your firm was registered with the United States Food and Drug Administration (FDA or Agency) as a manufacturer of several active pharmaceutical ingredients (APIs). A review of import records showed multiple shipments of API into the U.S. which declared Chengdu KeCheng Fine Chemicals Co., Ltd. as the drug manufacturer. On July 18, 2022, the FDA sent an electronic request for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 374(a)(4), to the contact e-mail address provided in your registration file. This request went unanswered. A second request was sent via email on August 8, 2022, followed by a telephone call from the FDA to you on October 24, 2022, regarding this matter. During the telephone call, you refused to provide your full name or an alternate email address for further communication. You stated that your firm was not shipping products to the U.S. and that you would deregister your firm as a drug establishment. However, your firm has continued to ship API to the U.S. as recently as January 2023. The Agency sent a follow-up electronic request for such records and other information on March 9, 2023. You failed to respond to these attempted communications or otherwise provide the requested records or other information. Pursuant to section 704(a)(4), FDA's request and follow-up communications included a sufficient and clear description of the records sought.

It is a prohibited act under section 301(e) of the FD&C Act (21 U.S.C. 331(e)) to refuse to permit access to or copying of any record as required by section 704(a). Because your API firm failed to respond to the section 704(a)(4) records requests and associated communication attempts, we have no indication of the level of quality assurance for drugs listed as manufactured at your facility.

FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-79 on June 8, 2023.

Until FDA is able to confirm compliance with CGMP and other applicable requirements, we may withhold approval of any new applications or supplements listing your firm as a drug manufacturer. In addition, shipments of articles manufactured at Chengdu KeCheng Fine Chemicals Co., Ltd., Floor 9, No. 18 Chuangye Road, Chengdu High-Tech District, Chengdu, Sichuan into the U.S. 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 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 3014675751 and ATTN: Joel Hustedt.

Sincerely,
/S/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research, FDA

CC:
Registered U.S. Agent
Santec Chemicals Corp.
96 Gazza Boulevard
Farmingdale, NY 11735
Email: wilson.jiao@santecchemcorp.com

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